BlueCross BlueShield of Arizona
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| **PHARMACY COVERAGE GUIDELINES** | **ORIGINAL EFFECTIVE DATE: 1/01/16** |
| **SECTION: DRUGS** | **LAST REVIEW DATE: 3/15/18** |
| | **LAST CRITERIA REVISION DATE: 3/15/18** |
| | **ARCHIVE DATE:** |

# SPRYCEL® (dasatinib) oral tablet

**Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.**

**This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.**

**The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.**

**The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.**

**State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.**

**Pharmacy Coverage Guidelines are subject to change as new information becomes available.**

**For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.**



This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

## SPRYCEL® (dasatinib) oral tablet (cont.)

**Description:**

Sprycel (dasatinib) is a kinase inhibitor is indicated for the treatment of adults with newly diagnosed with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase; chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib; Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy; and for the treatment of pediatric patients with Ph+ CML in chronic phase.

Dasatinib inhibits several kinases. It is predicted to bind to multiple conformations of the ABL kinase. *In vitro*, dasatinib was active in leukemic cell lines representing variants of imatinib-sensitive and -resistant disease. Dasatinib inhibited the growth of CML and ALL cell lines that overexpress BCR-ABL. Under the conditions of the assays, dasatinib was able to overcome imatinib-resistance resulting from BCR-ABL kinase domain mutations, activation of alternate signaling pathways involving the SRC family kinases (LYN, HCK), and multi-drug resistance gene overexpression.

# Sprycel (dasatinib)

**Medication class:**
Tyrosine kinase inhibitor

**FDA-approved indication(s):**
- Treatment of adults with newly diagnosed with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase
- Treatment of chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib
- Treatment of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy
- Treatment of pediatric patients with Ph+ CML in chronic phase

**Recommended Dose:**

Dosage
- Ph+ CML, chronic phase: 100 mg once daily.
- Ph+ CML, accelerated phase, or myeloid or lymphoid blast phase: 140 mg once daily
- Ph+ ALL: 140 mg once daily
- Chronic phase CML in pediatrics: starting dose based on body weight.

***Maximum dosage***
- Ph+ CML chronic phase: 140 mg once daily
- Ph+ CML advanced phase: 180 mg once daily
- Ph+ ALL: 180 mg once daily

**Available Dosage Forms:**
- 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg tablets

**Warnings and Precautions:**

## SPRYCEL® (dasatinib) oral tablet (cont.)

- Permanently discontinue with confirmed pulmonary arterial hypertension
  - Signs & symptoms may include: shortness of breath at rest, dizziness, chest pressure, fatigue, cough, tachycardia, fainting
- Permanently discontinue with severe mucocutaneous dermatologic reactions such as Stevens-Johnson syndrome and erythema multiforme
- Use with strong CYP3A4 inducers should be avoided, consider an increase in Sprycel dose if unavoidable
- Use with strong CYP3A4 inhibitors increases Sprycel levels, consider a decrease in Sprycel dose if unavoidable
- Solubility of Sprycel is pH dependent, use with a PPI or H2 receptor antagonist is not recommended, administration of antacid should be 2 hours before or after dose of Sprycel
- Woman of child bearing potential should use effective contraception
- Woman who is breast feeding an infant or child should stop breast feeding
- Bleeding
  - Signs & symptoms may include: unusual bleeding or easy bruising, dark red or tar-like stools
- Marked fluid retention
  - Signs & symptoms may include: swelling or feet, weight gain, peripheral edema
- Pleural effusion
  - Signs & symptoms may include: shortness of breath, cough, sharp chest pain
- Effects on Growth and Development in Pediatric Patients: epiphyses delayed fusion, osteopenia, growth retardation, and gynecomastia have been reported. Monitor bone growth and development in pediatric patients.

**Criteria:**

- **Criteria for initial therapy:** Sprycel (dasatinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is an Oncologist

2. Individual is 18 years of age or older

3. A confirmed diagnosis of **ONE** of the following:
   - Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (**Ph+ CML**) in chronic phase for adults
   - Chronic, accelerated, or myeloid or lymphoid **blast phase Ph+ CML** resistance or intolerance to prior therapy including imatinib
   - Philadelphia chromosome-positive acute lymphoblastic leukemia **(Ph+ ALL)** with resistance or intolerance to prior therapy
   - Individual is a pediatric patient with Ph+ CML in chronic phase

4. Philadelphia chromosome testing is positive for the Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) 1 fusion gene

## SPRYCEL® (dasatinib) oral tablet (cont.)

5. BCR-ABL1 mutation profile shows any of the following mutations: Y253H, E255K/V, or F358V/C/I for Ph+ CML or Ph+ AML

- **Initial approval duration:**
  - Up to Ph+ CML chronic phase: 140 mg once daily x 6 months
  - Ph+ CML advanced phase: 180 mg once daily x 6 months
  - Ph+ ALL: 180 mg once daily x 6 months

➢ **Criteria for continuation of coverage (renewal request):** Sprycel is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Continues to be seen by an Oncologist
2. The cancer has not progressed while on therapy
3. Individual has been adherent with the medication
4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use, such as:
   - Bleeding
   - Marked fluid retention
   - Pleural effusion
   - Pulmonary hypertension
5. There are no significant interacting drugs

- **Renewal duration:**
  - Up to Ph+ CML chronic phase: 140 mg once daily x 6 months
  - Ph+ CML advanced phase: 180 mg once daily x 6 months
  - Ph+ ALL: 180 mg once daily x 6 months

**Resources:**

Sprycel. Package Insert. Revised by manufacturer 05/2014. Accessed 08-04-2015.

Sprycel. Package Insert. Revised by manufacturer 10/2015. Accessed 07-22-2016.

Sprycel. Package Insert. Revised by manufacturer 04/2017. Accessed 07-27-2017.

Sprycel. Package Insert. Revised by manufacturer 11/2017. Accessed 02-23-2018.

NCCN Clinical Practice Guidelines in Oncology: Chronic myeloid leukemia. Version 01.2018, July 26, 2017. https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf

## **SPRYCEL® (dasatinib) oral tablet** (cont.)

UpToDate: Overview of the treatment of chronic myeloid leukemia. Current through Aug 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/overview-of-the-treatment-of-chronic-myeloid-leukemia?source=search_result&search=chronic%20myeloid%20leukemia&selectedTitle=2~150

UpToDate: Initial treatment of chronic myeloid leukemia in chronic phase. Current through Aug 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/initial-treatment-of-chronic-myeloid-leukemia-in-chronic-phase?source=see_link#H15

UpToDate: Treatment of chronic myeloid leukemia in chronic phase after failure of initial therapy. Current through Aug 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/treatment-of-chronic-myeloid-leukemia-in-chronic-phase-after-failure-of-initial-therapy?source=search_result&search=chronic%20myeloid%20leukemia&selectedTitle=4~150

NCCN Clinical Practice Guidelines in Oncology: Acute lymphoblastic leukemia. Version 02.2017, Aug 30, 2017. https://www.nccn.org/professionals/physician_gls/pdf/all.pdf

UpToDate: Induction therapy for Philadelphia chromosome positive acute lymphoblastic leukemia in adults. Current through Aug 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/induction-therapy-for-philadelphia-chromosome-positive-acute-lymphoblastic-leukemia-in-adults?source=see_link#H60604746

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

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**Fax completed prior authorization request form to 602-864-3126** or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

# Pharmacy Prior Authorization Request Form

**Do not copy for future use. Forms are updated frequently.**
**REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.**

## Member Information

| Member Name (first & last): | Date of Birth: | Gender: | BCBSAZ ID#: |
|---|---|---|---|
| Address: | City: | State: | Zip Code: |

## Prescribing Provider Information

| Provider Name (first & last): | Specialty: | NPI#: | DEA#: |
|---|---|---|---|
| Office Address: | City: | State: | Zip Code: |
| Office Contact: | Office Phone: | Office Fax: | |

## Dispensing Pharmacy Information

| Pharmacy Name: | Pharmacy Phone: | Pharmacy Fax: |
|---|---|---|

## Requested Medication Information

| Medication Name: | Strength: | Dosage Form: |
|---|---|---|
| Directions for Use: | Quantity: / Refills: | Duration of Therapy/Use: |

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

## Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

## Clinical Information

1. **What is the diagnosis? Please specify below.**

   **ICD-10 Code:** _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

| Medication Name, Strength, Frequency | Dates started and stopped or Approximate Duration | Describe response, reason for failure, or allergy |
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5. **Are there any supporting labs or test results? Please specify below.**

| Date | Test | Value |
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# Pharmacy Prior Authorization Request Form

**6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.**
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

**Signature affirms that information given on this form is true and accurate and reflects office notes**

Prescribing Provider's Signature: Date:

**Please note**: Some medications may require completion of a drug-specific request form.

**Incomplete forms or forms without the chart notes will be returned.**

Office notes, labs, and medical testing relevant to the request that show medical justification are required.