SPRYCEL®
dasatinib 100 mg tablets

Bristol Myers Squibb®
Access Support®

A REFERENCE GUIDE TO

Reimbursement and Coding for SPRYCEL® (dasatinib)

Please see Important Safety Information on pages 8-12 and US Full Prescribing Information.

Indications

SPRYCEL® (dasatinib) is indicated for the treatment of adult patients with:

- Newly diagnosed 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

SPRYCEL® is indicated for the treatment of pediatric patients 1 year of age and older with:

- Newly diagnosed Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) in combination with chemotherapy
- Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase

Summary of Warnings and Precautions

SPRYCEL is associated with the following warnings and precautions: myelosuppression, bleeding-related events, fluid retention, cardiovascular toxicity, pulmonary arterial hypertension, QT prolongation, severe dermatologic reactions, tumor lysis syndrome, embryo-fetal toxicity, and hepatotoxicity.

Please see Important Safety Information on pages 8-12 and US Full Prescribing Information.

For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday, or visit www.BMSAccessSupport.com.

Bristol Myers Squibb Is Committed to Helping Support Access

This brochure is designed to help appropriate patients get access to our medications by providing helpful reimbursement information to healthcare offices. Healthcare benefits vary significantly; therefore, it is important that oncology offices verify each patient's insurance coverage prior to initiating therapy.

Table of Contents

Healthcare providers should code healthcare claims based upon the service that is rendered, the patient's medical record, the coding requirements of each health insurer, and the best coding practices. The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

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ICD-10-CM codes for SPRYCEL® (dasatinib)

As an oral medication, there are no assigned J-codes, C-codes, or other HCPCS codes for SPRYCEL.

ICD-10-CM codes are used to identify a patient's diagnosis. On October 1, 2015, the newest version of these codes, ICD-10-CM, was implemented throughout the United States.

- The ICD-10-CM diagnosis codes contain **categories, subcategories**, and **codes**. Characters for categories, subcategories, and codes may be letters or numerals
- **All categories** are 3 characters
- **Subcategories** are either 4 or 5 characters
- **Codes** may be 3, 4, 5, 6, or 7 characters

The ICD-10-CM codes for the labeled indications for SPRYCEL are provided below by Bristol Myers Squibb and should be verified with the payer. Some health plan and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record. For additional coding questions, call BMS Access Support® at **1-800-861-0048** or visit **www.BMSAccessSupport.com**

ICD-10-CM Codes for SPRYCEL in Adult Acute Lymphoblastic Leukemia[1]	
C91 Lymphoid leukemia	
C91.0	**Acute lymphoblastic leukemia (ALL)***
C91.00	ALL, not having achieved remission
C91.01	ALL, in remission
C91.02	ALL, in relapse

ICD-10-CM Codes for SPRYCEL in Pediatric Acute Lymphoblastic Leukemia[1]	
C91 Lymphoid leukemia	
C91.0	**Acute lymphoblastic leukemia (ALL)***
C91.00	ALL, not having achieved remission
C91.01	ALL, in remission

*This is a category code and is invalid for stand-alone use.

HCPCS = Healthcare Common Procedure Coding System

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ICD-10-CM codes for SPRYCEL® (dasatinib) (cont'd)

ICD-10-CM Codes for SPRYCEL in Adult Chronic Myeloid Leukemia[1]	
C92 Myeloid leukemia	
C92.1	**Chronic myeloid leukemia (CML), BCR/ABL-positive***
C92.10	CML, BCR/ABL-positive, not having achieved remission
C92.11	CML, BCR/ABL-positive, in remission
C92.12	CML, BCR/ABL-positive, in relapse

ICD-10-CM Codes for SPRYCEL in Pediatric Chronic Myeloid Leukemia[1]	
C92 Myeloid leukemia	
C92.1	**Chronic myeloid leukemia (CML), BCR/ABL-positive***
C92.10	CML, BCR/ABL-positive, not having achieved remission
C92.11	CML, BCR/ABL-positive, in remission
C92.12	CML, BCR/ABL-positive, in relapse

*This is a category code and is invalid for stand-alone use.

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5010 Electronic Transaction Coding for SPRYCEL® (dasatinib)

The National Drug Codes (NDCs) for SPRYCEL, listed in the table below, are often necessary.

5010 Electronic Transaction Coding for SPRYCEL		
How Supplied[2]	NDC[2]	Billing NDC for NCPDP D.0 Pharmacy Claim Submission[3,4]
20 mg tablet, 60 tablets/bottle	0003-0527-11	00003-0527-11
50 mg tablet, 60 tablets/bottle	0003-0528-11	00003-0528-11
70 mg tablet, 60 tablets/bottle	0003-0524-11	00003-0524-11
80 mg tablet, 30 tablets/bottle	0003-0855-22	00003-0855-22
100 mg tablet, 30 tablets/bottle	0003-0852-22	00003-0852-22
140 mg tablet, 30 tablets/bottle	0003-0857-22	00003-0857-22

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Dosing for SPRYCEL® (dasatinib)

Dosage of SPRYCEL in Adult Patients	
100 mg once daily	Recommended starting dose for chronic phase Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) patients
140 mg once daily	Recommended starting dose for accelerated or myeloid or lymphoid blast phase Ph+ CML, or Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL)

Dosage of SPRYCEL Tablets for Pediatric Patients*[2]	
Body Weight (kg)†	**Daily Dose (mg)**
10 to less than 20	40 mg
20 to less than 30	60 mg
30 to less than 45	70 mg
at least 45	100 mg
This chart represents starting doses for pediatric patients. The recommended starting dosage for pediatrics is based on body weight. The recommended dose should be administered orally once daily with or without food. Recalculate the dose every 3 months based on changes in body weight, or more often if necessary.	

*For pediatric patients with Ph+ ALL, begin SPRYCEL therapy on or before day 15 of induction chemotherapy, when diagnosis is confirmed and continue for 2 years.[2]

†Tablet dosing is not recommended for patients weighing less than 10 kg.[2]

Tablets should not be crushed, cut, or chewed; they should be swallowed whole. SPRYCEL can be taken with or without a meal, either in the morning or in the evening.[2]

Please see US Full Prescribing Information for dose modification, dose escalation, dose adjustment for adverse reactions, and duration of treatment information.

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Important Safety Information

Myelosuppression:

Treatment with SPRYCEL is associated with severe (NCI CTCAE Grade 3/4) thrombocytopenia, neutropenia, and anemia, which occur earlier and more frequently in patients with advanced phase CML or Ph+ ALL than in patients with chronic phase CML. Myelosuppression was reported in patients with normal baseline laboratory values as well as in patients with pre-existing laboratory abnormalities.

- In patients with chronic phase CML, perform complete blood counts (CBCs) every 2 weeks for 12 weeks, then every 3 months thereafter, or as clinically indicated
- In patients with advanced phase CML or Ph+ ALL, perform CBCs weekly for the first 2 months and then monthly thereafter, or as clinically indicated
- In pediatric patients with Ph+ ALL treated with SPRYCEL in combination with chemotherapy, perform CBCs prior to the start of each block of chemotherapy and as clinically indicated. During the consolidation blocks of chemotherapy, perform CBCs every 2 days until recovery
- Myelosuppression is generally reversible and usually managed by withholding SPRYCEL temporarily and/or dose reduction
  – In clinical studies, myelosuppression may have also been managed by discontinuation of study therapy
  – Hematopoietic growth factor has been used in patients with resistant myelosuppression

Bleeding-Related Events:

SPRYCEL can cause serious and fatal bleeding. In all CML or Ph+ ALL clinical studies, Grade ≥3 central nervous system (CNS) hemorrhages, including fatalities, occurred in <1% of patients receiving SPRYCEL. The incidence of Grade 3/4 hemorrhage occurred in 5.8% of patients and generally required treatment interruptions and transfusions. The incidence of Grade 5 hemorrhage occurred in 0.4% of adult patients. The most frequent site of hemorrhage was gastrointestinal.

- Most bleeding events in clinical studies were associated with severe thrombocytopenia
- In addition to causing thrombocytopenia in human subjects, dasatinib caused platelet dysfunction *in vitro*
- Concomitant medications that inhibit platelet function or anticoagulants may increase the risk of hemorrhage

Fluid Retention:

SPRYCEL may cause fluid retention. After 5 years of follow-up in the randomized newly diagnosed chronic phase CML study (n=258), grade 3/4 fluid retention was reported in 5% of patients, including 3% of patients with grade 3/4 pleural effusion. In adult patients with newly diagnosed or imatinib-resistant or -intolerant chronic phase CML, grade 3/4 fluid retention occurred in 6% of patients treated with SPRYCEL at the recommended dose (n=548).

In patients with advanced phase CML or Ph+ ALL treated with SPRYCEL at the recommended dose (n=304), grade 3/4 fluid retention was reported in 8% of patients, including grade 3/4 pleural effusion reported in 7% of patients.

In pediatric patients with chronic phase CML, cases of Grade 1 or 2 fluid retention were reported in 10.3% of patients.

- Patients who develop symptoms of pleural effusion or other fluid retention, such as new or worsened dyspnea on exertion or at rest, pleuritic chest pain, or dry cough should be evaluated promptly with a chest x-ray or additional diagnostic imaging as appropriate
- Fluid retention events were typically managed by supportive care measures that may include diuretics or short courses of steroids
- Severe pleural effusion may require thoracentesis and oxygen therapy
- Consider dose reduction or treatment interruption

(continued on next page)

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Important Safety Information (cont'd)

Cardiovascular Toxicity:

SPRYCEL can cause cardiac dysfunction. After 5 years of follow-up in the randomized, newly diagnosed chronic phase CML trial (n=258), the following cardiac adverse reactions occurred:

- Cardiac ischemic events (3.9% dasatinib vs 1.6% imatinib), cardiac-related fluid retention (8.5% dasatinib vs 3.9% imatinib), and conduction system abnormalities, most commonly arrhythmia and palpitations (7.0% dasatinib vs 5.0% imatinib). Two cases (0.8%) of peripheral arterial occlusive disease occurred with imatinib and 2 (0.8%) transient ischemic attacks occurred with dasatinib

Monitor patients for signs or symptoms consistent with cardiac dysfunction and treat appropriately.

Pulmonary Arterial Hypertension (PAH):

SPRYCEL may increase the risk of developing PAH, which may occur any time after initiation, including after more than 1 year of treatment. Manifestations include dyspnea, fatigue, hypoxia, and fluid retention. PAH may be reversible on discontinuation of SPRYCEL.

- Evaluate patients for signs and symptoms of underlying cardiopulmonary disease prior to initiating SPRYCEL and during treatment. If PAH is confirmed, SPRYCEL should be permanently discontinued

QT Prolongation:

SPRYCEL may increase the risk of prolongation of QTc in patients including those with hypokalemia or hypomagnesemia, patients with congenital long QT syndrome, patients taking antiarrhythmic medicines or other medicinal products that lead to QT prolongation, and cumulative high-dose anthracycline therapy.

- Correct hypokalemia or hypomagnesemia prior to and during SPRYCEL administration

Severe Dermatologic Reactions:

Cases of severe mucocutaneous dermatologic reactions, including Stevens-Johnson syndrome and erythema multiforme, have been reported in patients treated with SPRYCEL.

- Discontinue permanently in patients who experience a severe mucocutaneous reaction during treatment if no other etiology can be identified

Tumor Lysis Syndrome (TLS):

TLS has been reported in patients with resistance to prior imatinib therapy, primarily in advanced phase disease.

- Due to potential for TLS, maintain adequate hydration, correct uric acid levels prior to initiating therapy with SPRYCEL, and monitor electrolyte levels
- Patients with advanced stage disease and/or high tumor burden may be at increased risk and should be monitored more frequently

Embryo-Fetal Toxicity:

Based on limited human data, SPRYCEL can cause fetal harm when administered to a pregnant woman. Hydrops fetalis, fetal leukopenia and fetal thrombocytopenia have been reported with maternal exposure to SPRYCEL. Transplacental transfer of dasatinib has been measured in fetal plasma and amniotic fluid at concentrations comparable to those in maternal plasma.

- Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with SPRYCEL and for 30 days after the last dose

(continued on next page)

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Important Safety Information (cont'd)

Effects on Growth and Development in Pediatric Patients:

In pediatric trials of SPRYCEL in chronic phase CML after at least 2 years of treatment, adverse reactions associated with bone growth and development were reported in 5 (5.2%) patients, one of which was severe in intensity (Growth Retardation Grade 3). These 5 cases included cases of epiphyses delayed fusion, osteopenia, growth retardation, and gynecomastia. Of these 5 cases, 1 case of osteopenia and 1 case of gynecomastia resolved during treatment.

Monitor bone growth and development in pediatric patients.

Hepatotoxicity:

SPRYCEL may result in hepatotoxicity as measured by elevation in bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase. Monitor transaminases at baseline and monthly or as clinically indicated during treatment. Reduce dose, withhold, or permanently discontinue SPRYCEL based on severity. When combined with chemotherapy, liver toxicity in the form of transaminase elevation and hyperbilirubinemia has been observed. Monitoring of hepatic function is recommended.

Lactation:

No data are available regarding the presence of dasatinib in human milk, the effects of the drug on the breastfed child, or the effects of the drug on milk production. However, dasatinib is present in the milk of lactating rats.

- Because of the potential for serious adverse reactions in nursing children from SPRYCEL, breastfeeding is not recommended during treatment with SPRYCEL and for 2 weeks after the last dose

Drug Interactions:

Effect of Other Drugs on Dasatinib

- **Strong CYP3A4 inhibitors:** The coadministration with strong CYP3A inhibitors may increase dasatinib concentrations. Increased dasatinib concentrations may increase the risk of toxicity. Avoid concomitant use of strong CYP3A4 inhibitors. If concomitant administration of a strong CYP3A4 inhibitor cannot be avoided, consider a SPRYCEL dose reduction

  – **Grapefruit juice** may increase plasma concentrations of SPRYCEL and should be avoided

- **Strong CYP3A4 inducers:** The coadministration of SPRYCEL with strong CYP3A inducers may decrease dasatinib concentrations. Decreased dasatinib concentrations may reduce efficacy. Consider alternative drugs with less enzyme induction potential. If concomitant administration of a strong CYP3A4 inducer cannot be avoided, consider a SPRYCEL dose increase

  – **St. John's wort** may decrease plasma concentrations of SPRYCEL and should be avoided

- **Gastric Acid Reducing Agents**: The coadministration of SPRYCEL with a gastric acid reducing agent may decrease the concentrations of dasatinib. Decreased dasatinib concentrations may reduce efficacy. Do not administer H_2 antagonists or proton pump inhibitors with SPRYCEL. Consider the use of antacids in place of H_2 antagonists or proton pump inhibitors. Administer the antacid at least 2 hours prior to or 2 hours after the dose of SPRYCEL. Avoid simultaneous administration of SPRYCEL with antacids.

(continued on next page)

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Important Safety Information for SPRYCEL® (dasatinib) (cont'd)

Adverse Reactions:

The safety data reflects exposure to SPRYCEL at doses tested in clinical studies (n=2712), including 324 adult patients with newly diagnosed chronic phase CML and 2388 adult patients with imatinib-resistant or -intolerant chronic or advanced phase Ph+ CML or Ph+ ALL.

The median duration of therapy in a total of 2712 SPRYCEL-treated adult patients was 19.2 months (range 0–93.2 months). Median duration of therapy in:

- 1618 adult patients with chronic phase CML was 29 months (range 0–92.9 months)
- 324 patients in the newly diagnosed chronic phase CML trial was approximately 60 months
- 1094 adult patients with advanced phase CML or Ph+ ALL was 6.2 months (range 0–93.2 months)

In the overall population of 2712 SPRYCEL-treated adult patients, 88% of patients experienced adverse reactions at some time and 19% experienced adverse reactions leading to treatment discontinuation.

Among the 1618 SPRYCEL-treated patients with chronic phase CML, drug-related adverse reactions leading to discontinuation were reported in 329 (20.3%) patients.

In the newly diagnosed chronic phase CML trial, drug was discontinued for adverse reactions in 16% of the adult patients with a minimum of 60 months of follow-up. After a minimum of 60 months of follow-up, the cumulative discontinuation rate was 39%.

Among the 1094 SPRYCEL-treated patients with advanced phase CML or Ph+ ALL, drug-related adverse reactions leading to discontinuation were reported in 191 (17.5%) patients.

Patients ≥65 years are more likely to experience the commonly reported adverse reactions of fatigue, pleural effusion, diarrhea, dyspnea, cough, lower gastrointestinal hemorrhage, and appetite disturbance, and more likely to experience the less frequently reported adverse reactions of abdominal distention, dizziness, pericardial effusion, congestive heart failure, hypertension, pulmonary edema and weight decrease, and should be monitored closely.

- In newly diagnosed chronic phase CML patients:
  - Drug-related serious adverse reactions (SARs) were reported for 16.7% of SPRYCEL-treated patients. Serious adverse reactions reported in ≥5% of patients included pleural effusion (5%)
  - The most common adverse reactions (≥15%) included myelosuppression, fluid retention, and diarrhea
  - Grade 3/4 laboratory abnormalities included neutropenia (29%), thrombocytopenia (22%), anemia (13%), hypophosphatemia (7%), hypocalcemia (4%), elevated bilirubin (1%), and elevated creatinine (1%)
- In adult patients resistant or intolerant to prior imatinib therapy:
  - Drug-related SARs were reported for 26.1% of SPRYCEL-treated patients treated at the recommended dose of 100 mg once daily in the randomized dose-optimization trial of patients with chronic phase CML resistant or intolerant to prior imatinib therapy. Serious adverse reactions reported in ≥5% of patients included pleural effusion (10%)
  - The most common adverse reactions (≥15%) included myelosuppression, fluid retention events, headache, diarrhea, fatigue, dyspnea, musculoskeletal pain, nausea, hemorrhage and skin rash
  - Grade 3/4 hematologic laboratory abnormalities in chronic phase CML patients resistant or intolerant to prior imatinib therapy who received SPRYCEL 100 mg once daily with a minimum follow up of 60 months included neutropenia (36%), thrombocytopenia (24%), and anemia (13%). Other grade 3/4 laboratory abnormalities included: hypophosphatemia (10%), and hypokalemia (2%)

(continued on next page)

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Important Safety Information (cont'd)

Adverse Reactions (cont'd):

- Grade 3/4 elevations of transaminases or bilirubin and Grade 3/4 hypocalcemia, hypokalemia, and hypophosphatemia were reported in patients with all phases of CML
  - Elevations in transaminases or bilirubin were usually managed with dose reduction or interruption
  - Patients developing Grade 3/4 hypocalcemia during the course of SPRYCEL therapy often had recovery with oral calcium supplementation

In a multicohort study of SPRYCEL administered continuously in combination with multiagent chemotherapy in 81 pediatric patients with newly diagnosed Ph+ ALL, the median duration of therapy was 24 months (range 2 to 27 months).

- In pediatric subjects with Ph+ ALL who were administered SPRYCEL in combination with multiagent chemotherapy:
  - Fatal adverse reactions occurred in 3 patients (4%), all of which were due to infections
  - Eight patients (10%) experienced adverse reactions leading to treatment discontinuation
  - The most common serious adverse reactions (incidence ≥10%) were pyrexia, febrile neutropenia, mucositis, diarrhea, sepsis, hypotension, infections (bacterial, viral and fungal), hypersensitivity, vomiting, renal insufficiency, abdominal pain, and musculoskeletal pain
  - The most common adverse reactions (≥30%) in pediatric patients receiving SPRYCEL in combination with chemotherapy included mucositis, febrile neutropenia, pyrexia, diarrhea, nausea, vomiting, musculoskeletal pain, abdominal pain, cough, headache, rash, fatigue, constipation, arrhythmia, hypertension, edema, infections (bacterial, viral and fungal), hypotension, decreased appetite, hypersensitivity, dyspnea, epistaxis, peripheral neuropathy, and altered state of consciousness
  - Grade 3/4 laboratory abnormalities (≥10%) included neutropenia (96%), thrombocytopenia (88%), anemia (82%), elevated SGPT (ALT) (47%), hypokalemia (40%), elevated SGOT (AST) (26%), hypocalcemia (19%), hyponatremia (19%), elevated bilirubin (11%), and hypophosphatemia (11%)

In two non-randomized trials in 97 pediatric patients with chronic phase CML (51 patients newly diagnosed and 46 patients resistant or intolerant to previous treatment with imatinib), the median duration of therapy was 51.1 months (range 1.9 to 99.6 months).

- Among the 97 CML pediatric subjects, drug-related adverse reactions leading to discontinuation were reported in 1 patient (1%)
- Drug-related serious adverse reactions were reported for 14.4% of pediatric patients
- Adverse reactions associated with bone growth and development were reported in 5 (5.2%) of pediatric patients with chronic phase CML
- The most common adverse reactions (≥15%) in pediatric patients included myelosuppression, headache, nausea, diarrhea, skin rash, pain in extremity, and abdominal pain.

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References

1. American Medical Association. 2018 ICD-10-CM: *The Complete Official Codebook.* Chicago, IL: American Medical Association; 2017.

2. SPRYCEL® (dasatinib) package insert. Princeton, NJ: Bristol-Myers Squibb Co.

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4. Optum - NCPDP Version D.0. Request Claim Billing Payer Sheet. https://www.optum.com/content/dam/optum3/optum/en/resources/guides/NCPDP_VERSION_D.0_PAYER_SHEET.pdf. Accessed October 26, 2018.

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Scheduling a meeting with a BMS Access and Reimbursement Manager on the BMS Access Support website

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