ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Urgent**[1] ☐ **Non-Urgent**

Requested Drug Name: Sprycel® (dasatinib)

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit: ☐ New Request ☐ Reauthorization

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Sprycel® (dasatinib)

Diagnosis (documentation supportive of diagnosis is required)

☐ Ph+ Acute Lymphoblastic Leukemia – resistant or intolerant to imatinib
☐ Ph+ Chronic Myeloid Leukemia – Chronic Phase – newly diagnosed
☐ Ph+ Chronic Myeloid Leukemia – Accelerated Phase – resistant or intolerant to imatinib
☐ Ph+ Chronic Myeloid Leukemia – Myeloid or Lymphoid Blast Phase – resistant or intolerant to imatinib
☐ Ph+ Chronic Myeloid Leukemia – Chronic Phase – resistant or intolerant to imatinib
☐ Other (please state): _____

Clinical Consideration

For all indications <u>EXCEPT</u> newly diagnosed Chronic Phase Ph+CML
☐ Patient has attempted therapy with Gleevec (imatinib) and is intolerant or refractory ***(documentation required)***

Physician Specialty

☐ Oncologist
☐ Other: _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	
Product will be delivered to: ☐ Patient's Home ☐ Physician Office		Other:
Prescriber or Authorized Signature:		Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request

Sprycel® (dasatinib)

CLASSIFICATION

- Antineoplastic Agent
- Tyrosine Kinase Inhibitor

DESCRIPTION

- Dasatinib is an inhibitor of multiple tyrosine kinases that is indicated for the treatment of chronic myeloid leukemia (CML) or Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy. It suppresses the growth and proliferation of leukemic cell lines over-expressing BCR-ABL and inhibits alternate signaling pathways involving the SRC family kinases.

Ph+ Acute Lymphoblastic Leukemia – resistant or intolerant to imatinib:

- Dasatinib is indicated in adults with Ph+ acute lymphoblastic leukemia who have demonstrated resistance or intolerance to prior therapy. Dasatinib produced hematologic and cytogenetic responses in patients with Philadelphia chromosome-positive (Ph+) acute lymphoid leukemia (ALL) who were resistant or intolerant to imatinib in an interim analysis of the single-arm START-L clinical trial (n=36).

Ph+ Chronic Myeloid Leukemia – Chronic Phase – Newly Diagnosed

- In a multinational, randomized, open-label, phase 3 trial (DASISION trial; n=519), dasatinib, compared with imatinib, produced a significantly higher confirmed complete cytogenetic response rate (CCyR) by 12 months and a higher confirmed CCyR at 24 months and 36 months in newly diagnosed patients with chronic-phase chronic myeloid leukemia.
- With 14 months of follow-up available from the DASISION (Dasatinib versus Imatinib Study in Treatment-Naïve CML-CP Patients) and the ENESTnd (Evaluating Nilotinib Efficacy and Safety in Clinical Trials-Newly Diagnosed Patients) trials, both dasatinib and nilotinib have emerged as first-line therapy for patients with chronic phase chronic myeloid leukemia (CML) based on superior major molecular response and cytogenetic response rates. While no head to head comparative studies have been performed between dasatinib and nilotinib, the previously mentioned studies suggest dasatinib and nilotinib have similar efficacy in their superiority over imatinib. The decision to use dasatinib or nilotinib as first-line therapy will likely be patient specific and based on the safety and tolerability profile of each of these agents.

Ph+ Chronic Myeloid Leukemia – Accelerated Phase – Resistant or intolerant to imatinib:

- Dasatinib provided significant hematologic response for treatment of chronic myelogenous leukemia-accelerated phase (CML-AP) previously resistant or intolerant to imatinib in the single-arm SRC/ABL Tyrosine Kinase Inhibition Activity Research Trials of Dasatinib (START A) study (n=174). In the imatinib-resistant CML-AP group, major hematologic response was achieved in 63% of patients and included a complete hematologic response in 45%. For the entire cohort, major hematologic response was achieved in 64%, including a complete hematologic response in 45% and major cytogenetic response (MCyR) occurred in 39%, with complete CyR in 32%. Median time to major hematologic response was 64 days, and median time to MCyRs was 58 days.

Ph+ Chronic Myeloid Leukemia – Myeloid or Lymphoid Blast Phase – Resistant or intolerant to imatinib:

- Dasatinib produced hematologic and cytogenetic responses in patients with *myeloid blast crisis*, Ph+ CML who were resistant or intolerant to imatinib in an interim analysis of the single-arm START-B trial (n=74). Overall hematologic response occurred in 53%, major hematologic responses in 34%, complete hematologic responses in 26%, and no evidence of leukemia (with incomplete recovery of neutrophils or platelets) in 8%. Major cytogenetic responses occurred in 31%, with complete cytogenetic responses in 27%.

- Dasatinib produced hematologic and cytogenetic responses in patients with *lymphoid blast crisis* (LBC), Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) who were resistant or intolerant to imatinib in an interim analysis of the single-arm START-L trial (n=78). Overall hematologic response occurred in 36%, major hematologic responses in 31%, complete hematologic responses in 26%, and no evidence of leukemia (with incomplete recovery of neutrophils or platelets) in 5%. Major cytogenetic responses occurred in 50%, with complete cytogenetic responses in 43%.

Ph+ Chronic Myeloid Leukemia – Chronic Phase – Resistant or intolerant to imatinib:

- In a randomized trial, dasatinib did not significantly improve major cytogenic response (MCyR) at 12 weeks compared with high-dose imatinib, but it did significantly improve MCyR, complete hematologic response, and complete cytogenic responses at 2 years. Dasatinib produced hematologic and cytogenetic responses in patients with chronic phase CML and imatinib resistance or intolerance in a single-arm study.
- In a randomized, dose optimization study, a dasatinib dose of 100 mg orally once daily, compared with a dose of 70 mg orally twice daily, significantly reduced adverse effects while maintaining efficacy.
- The most common adverse reactions (15% or greater) in patients with newly diagnosed chronic phase CML included myelosuppression, fluid retention, and diarrhea. The most common adverse reactions (20% or greater) in patients with resistance or intolerance to prior imatinib therapy included myelosuppression, fluid retention events, diarrhea, headache, dyspnea, skin rash, fatigue, nausea, and hemorrhage.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 3
Commercial Formulary: Tier 3
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Sprycel® (dasatinib) meets the definition of **medical necessity** for the following:

Documentation supportive of diagnosis is required.

- Ph+ Acute Lymphoblastic Leukemia – Resistant or intolerant to imatinib
- Ph+ Chronic Myeloid Leukemia – Chronic Phase – Newly Diagnosed
- Ph+ Chronic Myeloid Leukemia – Accelerated Phase – Resistant or intolerant to imatinib
- Ph+ Chronic Myeloid Leukemia – Myeloid or Lymphoid Blast Phase – Resistant or intolerant to imatinib
- Ph+ Chronic Myeloid Leukemia – Chronic Phase – Resistant or intolerant to imatinib

Documentation required demonstrating the patient has attempted therapy with Gleevec (imatinib) and is intolerant or refractory for all indications <u>EXCEPT</u> newly diagnosed Chronic Phase Ph+CML:

Sprycel® (dasatinib) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported

Required Provider Specialty:

- Approval is limited to Oncologists

DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined for pediatric patients less than 18 years):
Normal dosing:

- **Accelerated phase chronic myeloid leukemia, Resistant or intolerant to prior therapy:**

    - 140 mg orally once daily, either morning or evening, with or without food; dose escalation to 180 mg/day was allowed in patients who did not achieve hematologic or cytogenetic response in clinical studies; continue until disease progression or intolerance.
- **Acute lymphoid leukemia, Philadelphia chromosome-positive, resistant or intolerant to prior therapy:**
    - 140 mg orally once daily, either morning or evening, with or without food; dose escalation to 180 mg/day was allowed in patients who did not achieve hematologic or cytogenetic response in clinical studies; continue until disease progression or intolerance.
- **Blastic phase chronic myeloid leukemia, Resistant or intolerant to prior therapy:**
    - 140 mg orally once daily, either morning or evening, with or without food; dose escalation to 180 mg/day was allowed in patients who did not achieve hematologic or cytogenetic response in clinical studies; continue until disease progression or intolerance.
- **Chronic phase chronic myeloid leukemia, Newly diagnosed:**
    - 100 mg orally once daily, either morning or evening, with or without food; dose escalation to 140 mg/day was allowed in patients who did not achieve hematologic or cytogenetic response in clinical studies; continue until disease progression or intolerance.
- **Chronic phase chronic myeloid leukemia, Resistant or intolerant to prior therapy:**
    - 100 mg orally once daily, either morning or evening, with or without food; dose escalation to 140 mg/day was allowed in patients who did not achieve hematologic or cytogenetic response in clinical studies; continue until disease progression or intolerance

Dosing in other disease states:

- Refer to Sprycel's complete prescribing information.

PRECAUTIONS

- Cardiac adverse events (i.e., myocardial infarction, left ventricular dysfunction, congestive heart failure, cardiomyopathy, diastolic dysfunction, and left ventricular dysfunction), including fatal myocardial infarction, have been reported.
- Concomitant use with H2-receptor antagonists or proton pump inhibitors is not recommended.
- Concomitant use of strong CYP3A4 inducers is not recommended. If coadministration with a strong CYP3A4 inducer (e.g., carbamazepine, dexamethasone, phenobarbital, phenytoin, rifabutin, rifampin) cannot be avoided: consider a dasatinib dose increase and closely monitor for dasatinib toxicity.
- Avoid coadministration with St John's wort.
- Avoid concomitant use with antacids.
- Concomitant use of strong CYP3A4 inhibitors should be avoided. If coadministration with an inhibitor (e.g., atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, voriconazole, grapefruit juice) cannot be avoided: consider a dasatinib dose decrease to 20 mg orally daily in patients receiving 100 mg daily and to 40 mg orally daily in patients receiving 140 mg daily doses. If coadministration of dasatinib 20 or 40 mg daily with an inhibitor is not tolerated: either discontinue the CYP3A4 inhibitor or withhold dasatinib until treatment with the inhibitor is completed. Upon discontinuation of concurrent inhibitor: allow a 1-week washout period before increasing dasatinib dose.
- Elderly patients have increased risk of toxicity.
- Fluid retention, some cases severe (e.g., pleural and pericardial effusion, severe pulmonary edema, severe ascites), has been reported.
- Hemorrhages, including CNS (some cases fatal) and gastrointestinal (some cases fatal), have occurred. Most bleeding events have been associated with severe thrombocytopenia.
- Severe myelosuppression (grade 3 or 4 thrombocytopenia, neutropenia, and anemia) has been reported. Monitoring and dose adjustment is recommended.
- Pulmonary arterial hypertension (PAH) may occur, including after more than 1 year of treatment. Monitoring is recommended. Discontinue Sprycel if PAH is confirmed.
- QTc prolongation has been reported. Use caution in patients with QTc prolongation or at increased risk (e.g., congenital long QT syndrome, concurrent use of antiarrhythmic medications, other medications which cause QT prolongation, cumulative high-dose anthracycline therapy, hypokalemia or hypomagnesemia) and correct hypokalemia and hypomagnesemia prior to Sprycel administration.

Billing/Coding information

HCPCS Coding:

J8999	Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

COST

- AWP (January 2011): Sprycel 100mg ORALLY (30): $9,458.10
  Sprycel 140mg ORALLY (30): $9,458.10
- AWP (March 2014): Sprycel 100mg ORALLY (30): $11,021.10
  Sprycel 140mg ORALLY (30): $11,021.10

COMMITTEE APPROVAL

- November 2006

GUIDELINE UPDATE INFORMATION

November 2006	Prior Authorization created
May 2014	Coverage Policy created

REFERENCES

- DRUGDEX®, accessed 05/12/2014.
- Product Information: Sprycel® (dasatinib), Tablet for Oral Use. Bristol-Myers Squibb Company, Princeton, NJ, 5/2014.