Prior Authorization Approval Criteria
Sprycel (dasatinib)

Generic name: dasatinib
Brand name: Sprycel
Medication class: Antineoplastic Agent

FDA-approved uses: Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. Chronic, accelerated, or myeloid or lymphoid blast phase chronic myeloid leukemia (CML) with resistance or intolerance to prior therapy, including imatinib. Philadelphia chromosome positive acute lymphoblastic leukemia with resistance or intolerance to prior therapy (Ph + ALL)

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- Must be prescribed by an oncologist or hematologist
- Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.
  - Or
  - Clinically diagnosed with Ph + ALL with resistance or intolerance to prior therapy.
  - Or
  - Clinically diagnosed with CML
    - Resistance to Gleevec (imatinib). Defined as failure to achieve a complete hematologic response within 3-6 months or major cytogenetic response by month 12 or progression of disease after a previous cytogenetic or hematologic response.
    - Intolerance to Gleevec (imatinib). Defined as the inability to tolerate 400 mg or more of imatinib per day or discontinuation of imatinib

Criteria for continuation of therapy:
- Patient’s therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the patient’s condition at this time.
- Patient is tolerating treatment
- Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient’s condition)

Approval Duration:
- Initial: 6 months
- Renewal: 1 year

Benefit Type:
- Pharmacy

** Off-label Use:
Fallon may authorize coverage of the requested medication for use in other cancer diagnoses with submitted documentation that the drug is recognized as a “Medically Accepted Indication” according to

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
Fallon Health Department of Pharmacy Services Page 1 of 2
the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus.

If the requested off-label use is not acknowledged by the NCCN Drugs and Biologics Compendium, Fallon will abide by the Centers for Medicare and Medicaid Services (CMS) guidance or Massachusetts regulations¹ accepting documentation of recommended off-label use of the requested medication in any one of the following:

1. One of the following standard reference compendia:
   - American Hospital Formulary Service – Drug information (AHFS-DI)
   - Thomson Micromedex DrugDex
   - Clinical Pharmacology (Gold Standard)
   - Wolters Kluwer Lexi-Drugs

2. Peer-reviewed published medical literature determined by Fallon that sufficient evidence exists to support use.

¹Reference: https://malegislate.gov/Laws/GeneralLaws/PartII/TitleXXII/Chapter175/Section47K accessed 7/7/2017

Adopted: 09/13/06