OVERVIEW:
Sprycel, a kinase inhibitor, is FDA approved for the treatment of adults 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 Gleevec® (imatinib tablets); and Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy. Currently, there are four other tyrosine kinase inhibitors (TKIs) approved for the treatment of Ph+ CML: Gleevec (imatinib tablets), Sprycel® (dasatinib tablets), Bosulif® (bosutinib tablets), Tasigna® (nilotinib capsules), and Iclusig® (ponatinib tablets). These agents are indicated for the treatment of Ph+ CML in various phases; some TKIs are indicated after resistance or intolerance to prior therapy. Iclusig is approved for patients with T315I-positive CML and in adult patients with CML for whom no other TKI therapy is indicated. Sprycel also has supportive evidence for those experiencing resistance or intolerance to other drug treatments and are diagnosed with gastrointestinal stromal tumor.

GUIDELINES:
The National Comprehensive Cancer Network (NCCN) guidelines for CML (version 2.2017) for newly diagnosed patients with Ph+ CML recommend Gleevec (400 mg once daily [QD]), Sprycel (100 mg QD), or Tasigna (300 mg twice daily [BID]) [category 1 recommendation]. Depending upon the agent chosen for initial therapy, if response is not achieved increasing the dose of Gleevec, or changing to an alternative TKI therapy is recommended. Iclusig is recommended for patients with a T315I mutation or for patients who have not responded to two or more TKI therapies. Other non-TKI medication therapies are also an option (e.g., Synribo™ [omecetaxine mepesuccinate for injection]). Participation in a clinical trial or allogeneic hematopoietic stem cell transplantation (HSCT) is also a reasonable treatment option for lack of response.

POLICY STATEMENT: In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist or oncologist.

Recommended Authorization Criteria
Coverage of Sprycel is recommended in those who meet the following criteria:


3. **Gastrointestinal Stromal Tumor (GIST).** Approve if the patient meets the following criteria (a, b, c **and** d):
   a) Patient has experienced resistance, intolerance or is unable to receive treatment with Gleevec (imatinib); AND
   b) Patient has experienced resistance, intolerance or is unable to receive treatment with Sutent (sunitinib); AND
   c) Patient has experienced resistance, intolerance or is unable to receive treatment with Stivarga (regorafenib); AND
   d) Patient has the D842V mutation.

4. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation.** Prescriber will provide specific diagnosis for documentation. Approve.

5. **Patient has been started on Sprycel.** Approve for an indication or condition addressed as an approval in this document.

**Approval Duration:** 365 days (1 year)

**References**

- Gleevec® tablets [prescribing information]. East Hanover, NJ: Novartis; September 2016.
- Tasigna® capsules [prescribing information]. East Hanover, NJ: Novartis; September 2016.