I. Medication Description

Sprycel is an oral multi-tyrosine kinase inhibitor that antagonizes the tyrosine kinase enzymes that have become resistant or intolerant to Gleevec (imatinib), another tyrosine kinase inhibiting drug used in treating patients with chronic myelogenous leukemia (CML). Alternatively, patients diagnosed with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) that have experienced resistance or intolerance to Gleevec therapy can use Sprycel.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Sprycel is available when the following criteria have been met:

- Member is at least 18 years of age AND
- The medication is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is available for up to 4200mg of dasatinib every 30 days.

V. Coverage Duration

Initial coverage is provided for 6 months and may be renewed in up to 12 month intervals dependent on member’s response to treatment.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Disease response shown in the form of a decrease in tumor size, decrease in tumor spread, cytogenic response, molecular response, etc AND
• Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Available as 20mg, 50mg, 70mg, 80mg, 100mg, and 140mg oral tablets.

VIII. Summary of Policy Changes

• 1/1/12:
  o Addition of GIST coverage
  o Gleevec trial required prior to coverage for CML accelerated or blast crisis phase
  o Requirement of Ph+ or BCR-ABL+ verification for first line use in CML in chronic phase
• 12/15/12:
  o updated criteria to include coverage for post-transplant use in CML, first-line therapy in ALL, secondary therapy for CML after Tasigna
  o clarification of ICD9 codes for coverage
  o coverage duration extended
  o removal of resistance/intolerance to imatinib therapy in Ph+ ALL patients from coverage criteria
• 12/15/13: policy updated in accordance with current NCCN CML recommendations
• 6/9/14: Single agent coverage in ALL removed; Included mutation status needed for coverage in soft tissue sarcoma to mirror NCCN guidelines
• 1/1/15: Removal of treatment for CML as follow up therapy after bosutinib and pontinib per updated NCCN compendium; Addition of specific mutations for when ALL salvage therapy is provided
• 7/1/15: formulary distinctions made
• 12/15/15: updated criteria for the treatment of GIST and for ALL per updated NCCN treatment guidelines
• 9/15/16: policy updated to correspond with current NCCN treatment guidelines
• 10/16/17: coverage criteria updated to allow use as supported by current NCCN guidelines
• 11/1/18: no policy changes
• 11/15/19: no policy changes

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.