I. Medication Description

Imatinib, a tyrosine kinase inhibitor, is considered to be one of the first clinically useful agents in a class of cancer agents called signal transduction inhibitors (STIs). STIs interfere with intracellular signaling pathways that have been implicated in the development of malignancies. Imatinib inhibits the bcr-abl tyrosine protein kinase, the constitutive abnormal tyrosine kinase created by the Philadelphia chromosome abnormality found in CML, ALL, and GIST. Imatinib inhibits proliferation and induces apoptosis in bcr-abl positive cell lines as well as fresh leukemic cells from Philadelphia chromosome positive chronic myeloid leukemia. Imatinib is also an inhibitor of the receptor tyrosine kinases for platelet-derived growth factor (PDGF) and stem cell factor (SCF), c-kit, and inhibits PDGF- and SCF-mediated cellular events.

II. Position Statement

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

III. Policy

Coverage of Gleevec or imatinib is available when the following criteria have been met:

- 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

- 100mg tablets: 240/month
- 400mg tablets: 60/month
- If higher doses are required due to concurrent use of a strong CYP3A4 inducer (i.e. carbamazepine, dexamethasone, phenobarbital, phenytoin, rifampin, etc), coverage may be granted upon request for up to 1200mg/day.

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 initial treatment.
VI. Coverage Renewal Criteria

Coverage can be renewed in up to 12 month intervals 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

Pertinent diagnoses:

• Chronic Myelogenous Leukemia: C92.10, C92.11, C92.12
• Lymphoblastic Lymphoma, Acute Lymphoblastic Leukemia: C91.00 – C91.01, C91.02
• Dermatofibrosarcoma protuberans: C44.90
• Gastrointestinal stromal tumor: C49.4, C49.8, C49.9, Z85.831
• Myelodysplastic syndrome (MDS)/myeloproliferative disease (MPD): C93.10
• Melanoma: C43.0, C43.10-C43.12, C43.20-C43.22, C43.30, C43.31, C43.39, C43.4, C43.51, C43.52, C43.59-C43.62, C43.70-C43.72, C43.8, C43.9, C79.31, C80.0, C80.1, Z85.820
• Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor (PVS/TGCT): D48.1
• Bone Cancer- Chordoma: C72.0 – C72.1
• Soft Tissue Sarcoma- Desmoid Tumors: D48.1, Z85.831

VIII. Summary of Policy Changes

• 4/1/11:
  o Addition of desmoid tumors indication
  o Addition of dosing table based on indication
  o Criteria for coverage in each indication specified
  o Duration of coverage limited to 6 months at a time
• 9/1/11: No changes
• 12/15/12: updated criteria to include first line usage in CML, for post-transplant use in CML, for melanoma, and for PVS/TGCT; removed C-KIT positive requirement for GIST treatment coverage
• 1/2013: updated criteria to allow coverage in children with newly-diagnosed Ph+ ALL per FDA approval
• 12/15/13:
  o Clarified age limits for coverage for individual diagnoses
  o Added criteria for bone cancer/chordoma
  o Updated desmoid tumor, ALL, CLL, and DFSP coverage criteria
  o Updated pertinent ICD9 codes
• 1/1/15: CLL and ALL criteria changed to reflect NCCN Guidelines; removed coverage for HES, CEL, and ASM to reflect NCCN Guidelines
• 7/1/15: formulary distinctions made
• 9/15/15: criteria updated to reflect NCCN Guidelines
• 7/19/16: policy updated to correspond with current NCCN treatment guidelines
Drug Therapy Guidelines  | Gleevec® (imatinib)  | Last Review Date: 5/2017

- 2/3/17: policy updated to correspond with current NCCN treatment guidelines for Dermatofibrosarcoma Protuberans
- 6/21/17: coverage criteria updated to allow use as supported by current NCCN guidelines

IX. References

1. UpToDate Online, retrieved 1/2017.

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.