PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Oncology – Imatinib Preferred Specialty Management Policy
- Imatinib (Gleevec® tablets – Novartis, generic)

REVIEW DATE: 05/04/2022

OVERVIEW

Imatinib, a tyrosine kinase inhibitor (TKI), is indicated for the treatment of:[1,2]

- **Acute lymphoblastic leukemia (ALL)**, Philadelphia chromosome positive (Ph+), in adults with relapsed or refractory disease.
- **ALL**, newly diagnosed and Ph+, in combination with chemotherapy in pediatric patients.
- **Aggressive systemic mastocytosis**, in adults, without the D816V c-Kit mutation or with unknown c-Kit mutational status.
- **Chronic myeloid leukemia (CML)**, newly diagnosed and Ph+, in adult and pediatric patients in chronic phase.
- **CML**, Ph+, in blast phase, accelerated phase, or in chronic phase after failure of interferon alfa therapy.
- **Dermatofibrosarcoma protuberans** in adults with unresectable, current, and/or metastatic disease.
- **Gastrointestinal stromal tumors (GIST)**, in patients with Kit (CD117) positive unresectable and/or metastatic malignant disease.
- **GIST**, Kit (CD117) positive, as adjuvant treatment of adults following resection.
- **Hypereosinophilic syndrome and/or chronic eosinophilic leukemia**, in adults who have the *FIP1L1-PDGFR* alpha fusion kinase (mutation analysis or fluorescence in situ hybridization demonstration of CICH2 allele deletion) for patients with HES and/or CEL who are *FIP1l1-PDGFR* alpha fusion kinase negative or unknown.
- **Myelodysplastic/myeloproliferative diseases**, associated with *PDGFR* gene rearrangements in adults.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the standard *Oncology – Imatinib Prior Authorization Policy* criteria. The program also directs the patient to try the Preferred Product prior to the approval of the Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). If the patient meets the standard *Oncology – Imatinib Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for a Preferred Product will be authorized. All approvals are provided for the duration noted below.

Documentation: Documentation will be required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, and prescription receipts.

Automation: None.

Preferred Product: generic imatinib tablets
Non-Preferred Product: Gleevec

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Gleevec	**1.** Approve for 1 year if the patient meets ALL of the following (A, B, and C): **A)** Patient meets the standard *Oncology – Imatinib Prior Authorization Policy* criteria; AND **B)** Patient has tried generic imatinib tablets; AND **C)** Patient cannot continue to use generic imatinib tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **2.** For a patient who has met the *Oncology – Imatinib Prior Authorization Policy* criteria, but has not met exception criteria (1B) and/or (1C): approve generic imatinib tablets for 1 year.

REFERENCES

1. Gleevec® tablets [prescribing information]. East Hanover, NJ: Novartis; March 2022.
2. Imatinib tablets [prescribing information]. Cranbury, NJ: Sun; April 2022.