PREFERRED SPECIALTY MANAGEMENT POLICY

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

REVIEW DATE: 05/31/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 (HES) and/or chronic eosinophilic leukemia (CEL)**, in adults who have the *FIP1L1-PDGFR* alpha fusion kinase (mutation analysis or fluorescence *in situ* hybridization demonstration of

CICH2 allele deletion) and 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.

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

Oncology – Imatinib non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT 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 take generic imatinib tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and bioequivalent generic product 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) above for brand Gleevec: 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	No criteria changes. The policy name was changed to reflect generic availability.	05/04/2022
Annual Revision	No criteria changes.	05/31/2023