MEDICAL MUTUAL®

Drug Policy

Policy:	Gleevec (imatinib mesylate)	Annual Review Date: 05/18/2023 Last Revised Date: 05/18/2023

OVERVIEW

Gleevec, a kinase inhibitor, is FDA indicated for the treatment of: adult and pediatric patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in chronic phase (CP); Ph+ CML in blast crisis (BC), accelerated phase (AP) or in CP after failure of interferon-alpha therapy; adult patients with relapsed or refractory Ph+ acute lymphoblastic leukemia (ALL); pediatric patients with newly diagnosed Ph+ positive ALL in combination with chemotherapy, adults with myelodysplastic/myeloproliferative disease (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements; adults with aggressive systemic mastocytosis (ASM); adults with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL); adults with unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (DFSP); and patients with gastrointestinal stromal tumors (GIST). Gleevec is also available as a generic. Currently, there are four other tyrosine kinase inhibitors (TKIs) approved for the treatment of Ph+ CML: Tasigna (nilotinib capsules), Sprycel (dasatinib tablets), Bosulif (bosutinib tablets), 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.

POLICY STATEMENT

This policy involves the use of Gleevec. Prior authorization is recommended for pharmacy benefit coverage of Gleevec. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Gleevec as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Gleevec be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Gleevec must be prescribed by or in consultation with a hematologist, oncologist, gastroenterologist, or transplant specialist. A trial of generic imatinib mesylate is required before approval of brand Gleevec for all new starts [documentation required]. Documentation must include chart notes, prescription claims records, prescription receipts and/or other information. All approvals for initial therapy are provided for the initial approval duration noted below.

Automation: When available, the following ICD-10 codes will be used for automation to allow approval of generic imatinib mesylate tablets: C92.1* (Ph+ CML, BCR-ABL1+ CML), C49.A* (GIST), D72.11 (HES), D47.5 (CEL), C94.6 (MDS), C47.1 (MPD).

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Gleevec (imatinib) is recommended in those who meet the following criteria:

For all indications: If brand Gleevec is prescribed, the patient must have tried generic imatinib mesylate tablets AND the patient cannot use generic imatinib due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] which, per the prescribing physician, would result in a significant allergy or serious adverse reaction [documentation required]; AND

1. **Philadelphia Chromosome Positive (Ph+) Chronic Myeloid Leukemia (CML)**
   Criteria. *Approve.*

2. **BCR-ABL1 Positive Chronic Myeloid Leukemia (CML)**
   Criteria. *Approve.*

3. **Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL)**
   Criteria. *Approve if the patient is 18 years of age or older or in pediatric patients younger than 18 if used in combination with chemotherapy.*

4. **Dermatofibrosarcoma Protuberans (DFSP)**
   Criteria. *Approve if the patient has unresectable, recurrent, metastatic DFSP OR DFSP with fibrosarcomatous transformation.*

5. **Gastrointestinal Stromal Tumors (GIST)**
   Criteria. *Approve.*

6. **Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)**
   Criteria. *Approve.*

7. **Aggressive Systemic Mastocytosis (ASM)**
   Criteria. *Approve if disease is KIT D816V mutation negative or unknown or if eosinophilia is present with FIP1L1-PDGFRA fusion gene.*

8. **Myelodysplastic/Myeloproliferative Disease (MDS/MPD) [e.g., Polycythemia Vera, myelofibrosis]**
   Criteria. *Approve.*

9. **Advanced Kaposi Sarcoma**
   Criteria. *Patient must meet the following criteria (A, B, and C):*

A. The patient has tried one first-line AND one alternate first-line systemic therapy regimen (e.g., liposomal doxorubicin, paclitaxel, Pomalyst [pomalidomide capsules], and Thalomid [thalidomide capsules]); AND
B. The patient has relapsed or refractory disease; AND
C. The patient continues to use antiretroviral therapy (ART) if HIV-positive

10. **Recurrent Conventional or Chrondroid Chordoma**
Criteria. *Approve.*

11. **Desmoid Tumors (Aggressive Fibromatosis)**
Criteria. *Approve.*

12. **Steroid-Refractory Chronic Graft-Versus-Host Disease (GVHD)**
Criteria. *Approve.*

13. **Metastatic or Unresectable Cutaneous Melanoma in patients for tumors with activating mutations of KIT**
Criteria. *Approve as a second line or subsequent therapy or after maximum clinical benefit from BRAF targeted therapy.*

14. **Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor (PVNS/TGCT)**
Criteria. *Approve if used as a single agent.*

15. **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**
Criteria. *Approve if patient has FIP1L1-PDGFRA or PDGFRB rearrangement or ABL1 rearrangement.*

16. **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**
Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

17. **Patient has been started on Gleevec**
Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Gleevec has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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