SPECIALTY GUIDELINE MANAGEMENT

GLEEVEC (imatinib mesylate)
imatinib mesylate (generic)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase
2. Patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy
3. Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
4. Pediatric patients with newly diagnosed Ph+ ALL in combination with chemotherapy
5. Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements as determined with an FDA-approved test
6. Adult patients with aggressive systemic mastocytosis without the D816V c-Kit mutation as determined with an FDA-approved test or with c-Kit mutational status unknown
7. Adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRα fusion kinase (mutational analysis or FISH demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRα fusion kinase negative or unknown
8. Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP)
9. Patients with Kit (CD117) positive unresectable and/or metastatic gastrointestinal stromal tumors (GIST)
10. Adjuvant treatment of adult patients following complete gross resection of Kit (CD117) positive GIST

B. Compendial Uses

1. Primary treatment of advanced phase CML (accelerated phase or blast phase)
2. Follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT)
3. Induction/consolidation and maintenance therapy for Ph+ ALL
4. GIST (primary, postoperative and continued treatment)
5. Desmoid tumors
6. Pigmented villonodular synovitis/tenosynovial giant cell tumor
7. Recurrent chordoma
8. Metastatic or unresectable C-Kit mutated melanoma as second-line or subsequent therapy
9. AIDS-related Kaposi sarcoma that has progressed on or not responded to first-line systemic therapy
10. Chronic myelomonocytic leukemia

All other indications are considered experimental/investigational and are not a covered benefit.
II. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review prior to initiation of therapy for treatment of CML or Ph+ ALL: results of cytogenetic and/or molecular testing for detection of the Ph chromosome or the BCR-ABL gene.

III. CRITERIA FOR INITIAL APPROVAL

A. Chronic Myeloid Leukemia (CML)
Authorization of 6 months may be granted for treatment of CML that has been confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing when the member did not fail (other than due to intolerance) prior therapy with a TKI (e.g., dasatinib, nilotinib, bosutinib, ponatinib).

B. Ph+ Acute Lymphoblastic Leukemia (ALL)/Lymphoblastic Lymphoma (LL)
Authorization of 12 months may be granted for treatment of Ph+ ALL or lymphoblastic lymphoma that has been confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing.

C. Gastrointestinal Stromal Tumor (GIST), Desmoid Tumors, Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor (PVNS/TGCT), Hypereosinophilic Syndrome/Chronic Eosinophilic Leukemia (HES/CEL), Dermatofibrosarcoma Protuberans (DFSP), Chordoma
Authorization of 12 months may be granted for treatment of GIST, desmoid tumors, PVNS/TGCT, HES/CEL, DFSP, or recurrent chordoma

D. Myelodysplastic Syndromes/Myeloproliferative Diseases (MDS/MPD) and Chronic Myelomonocytic Leukemia (CMML)
Authorization of 12 months may be granted for treatment of MDS/MPD or CMML when the member’s disease is associated with PDGFR gene rearrangements

E. Aggressive Systemic Mastocytosis (ASM)
Authorization of 12 months may be granted for treatment of ASM without the D816V c-Kit mutation or with c-Kit mutational status unknown.

F. Melanoma
Authorization of 12 months may be granted for treatment of metastatic or unresectable c-Kit mutation-positive melanoma as second-line or subsequent therapy.

G. AIDS-related Kaposi Sarcoma
Authorization of 12 months may be granted for treatment of AIDS-related Kaposi sarcoma that has progressed on or not responded to first-line systemic therapy.

IV. CONTINUATION OF THERAPY

A. CML
Authorization of 12 months may be granted for continued treatment of CML that has been confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing when any of the following criteria are met:
1. BCR-ABL1 ≤ 10% for members who have been receiving imatinib/Gleevec for ≤ 12 months
2. No evidence of disease progression for members who have been receiving imatinib/Gleevec for > 12 months
3. Member has received HSCT

B. Ph+ ALL/LL
Authorization of 12 months may be granted for continued treatment of Ph+ ALL or LL that has been confirmed by detection of Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing in members who have not experienced disease progression or an unacceptable toxicity.

C. GIST, Desmoid Tumors, PVNS/TGCT, HES/CEL, DFSP, Chordoma, MDS/MPD, CMML, ASM, Melanoma, AIDS-related Kaposi sarcoma
Authorization of 12 months may be granted for continued treatment of GIST, desmoid tumors, PVNS/TGCT, HES/CEL, DFSP, recurrent chordoma, MDS/MPD, CMML, ASM, metastatic or unresectable melanoma, or AIDS-related Kaposi sarcoma in members who have not experienced disease progression or an unacceptable toxicity.

V. REFERENCES