Reference number(s)
2172-A

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[1,2]
1. Treatment of newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase
2. Treatment of patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy
3. Treatment of adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
4. Treatment of pediatric patients with newly diagnosed Ph+ ALL in combination with chemotherapy
5. Treatment of 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. Treatment of 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. Treatment of 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. Treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP)
9. Treatment of patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST)
10. Adjuvant treatment of adult patients following complete gross resection of Kit (CD117) positive GIST

B. Compendial Uses[3-5]
1. Treatment of patients with advanced phase CML (accelerated phase or blast phase)
2. Follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT)
3. Ph+ ALL/lymphoblastic lymphoma
4. GIST (primary, preoperative, postoperative and continued treatment)
5. Desmoid tumors
6. Pigmented villonodular synovitis/tenosynovial giant cell tumor
7. Chordoma
8. C-Kit mutated melanoma
9. AIDS-related Kaposi sarcoma

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Chronic Myelogenous Leukemia (CML)[1-4]
Authorization of 12 months may be granted for the treatment of CML when BOTH of the following criteria are met:
1. Diagnosis of CML was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing
2. 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[1-3,5]
Authorization of 12 months may be granted for the treatment of Ph+ ALL/lymphoblastic lymphoma when diagnosis of Ph+ ALL/lymphoblastic lymphoma was 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[1-3]
Authorization of 12 months may be granted for the treatment of GIST, desmoid tumors, PVNS/TGCT, HES/CEL, DFSP, or chordoma

D. Myelodysplastic Syndromes and Myeloproliferative Diseases (MDS/MPD)[1,2]
Authorization of 12 months may be granted for the treatment of MDS or MPD when the member's disease is associated with PDGFR gene rearrangements

E. Aggressive Systemic Mastocytosis (ASM)[1,2]
Authorization of 12 months may be granted for the treatment of ASM without the D816V c-Kit mutation or with c-Kit mutational status unknown

F. Melanoma[3]
Authorization of 12 months may be granted for the treatment of c-Kit mutation-positive melanoma

G. AIDS-related Kaposi sarcoma[3]
Authorization of 12 months may be granted for the treatment of AIDS-related Kaposi sarcoma

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL diagnosis-specific authorization criteria below:

A. Chronic Myelogenous Leukemia (CML)[1-4]

Authorization of up to 12 months may be granted for the treatment of CML when ALL of the following criteria are met:

1. Diagnosis of CML was confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing
2. Member did not fail (other than due to intolerance) prior therapy with a TKI (e.g., dasatinib, nilotinib, bosutinib, ponatinib)
3. Member meets ANY of the following criteria:
   a. CML is in chronic phase and member is receiving benefit from therapy (i.e., achieved or maintained a cytogenic or molecular response to therapy).
   b. CML is in accelerated or blast phase CML
   c. Member has received a HSCT for CML (any phase)

B. Ph+ Acute Lymphoblastic Leukemia (ALL)/lymphoblastic lymphoma, Melanoma, Myelodysplastic Syndromes and Myeloproliferative Diseases (MDS/MPD), Aggressive Systemic Mastocytosis (ASM), 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, AIDS-related Kaposi sarcoma[1-5]

All members (including new members) requesting authorization for continuation of therapy for Ph+ ALL/lymphoblastic lymphoma, melanoma, MDS/MPD, ASM, GIST, desmoid tumors, PVNS/TGCT, HES/CEL, DFSP, chordoma or AIDS-related Kaposi sarcoma must meet ALL initial authorization criteria

IV. REFERENCES

1. Gleevec [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2017.
2. imatinib [package insert]. Cranbury, NJ: Sun Pharmaceuticals Inc.; October 2017.
3. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 30, 2018.
4. The NCCN Clinical Practice Guidelines in Oncology® Chronic Myelogenous Leukemia (Version 4.2018). © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 30, 2018.
5. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 30, 2018.