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. 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
6. Treatment of adult patients with aggressive systemic mastocytosis without the D816V c-Kit mutation 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
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. DFSP, for adjuvant treatment following resection
5. GIST (primary, preoperative, postoperative and continued treatment)
6. Desmoid tumors
7. Pigmented villonodular synovitis/tenosynovial giant cell tumor
8. Chordoma
9. C-Kit mutated melanoma

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 for members requesting authorization of Gleevec for CML or Ph+ ALL: Results of cytogenetic and/or molecular testing for detection of the Ph chromosome or the BCR-ABL gene obtained prior to initiation of therapy

III. CRITERIA FOR INITIAL APPROVAL

A. Chronic Myelogenous Leukemia (CML)
Authorization of 12 months may be granted for members initiating Gleevec 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
Authorization of 12 months may be granted for members initiating Gleevec 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
Authorization of 12 months may be granted for members initiating Gleevec for the treatment of GIST, desmoid tumors, PVNS/TGCT, HES/CEL, DFSP, or chordoma

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

E. Aggressive Systemic Mastocytosis (ASM)
Authorization of 12 months may be granted for members initiating Gleevec for the 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 members initiating Gleevec for the treatment of c-Kit mutation-positive melanoma

IV. 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)
Authorization of up to 12 months may be granted for members continuing Gleevec 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. Authorization of up to 12 months for members with chronic phase CML who have been receiving Gleevec for < 12 months
   b. Authorization of 12 months for members with chronic phase CML who have been receiving Gleevec for ≥12 months and have achieved or maintained a cytogenic or molecular response to therapy

c. Authorization of 12 months for members with accelerated or blast phase CML
d. Authorization of 12 months for members who have 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
All members (including new members) requesting authorization for continuation of Gleevec therapy for Ph+ ALL, melanoma, MDS/MPD, ASM, GIST, desmoid tumors, PVNS/TGCT, HES/CEL, DFSP or chordoma must meet ALL initial authorization criteria

V. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The following dosing limits apply: 800mg per day.

VI. REFERENCES

1. Gleevec [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2015.
2. imatinib [package insert]. Cranbury, NJ: Sun Pharmaceuticals Inc.; January 2016.
3. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 3, 2016.
4. The NCCN Clinical Practice Guidelines in Oncology® Chronic Myelogenous Leukemia (Version 1.2016). © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 3, 2016.
5. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 2.2015). © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 3, 2016.