

Specialty Pharmacy Program

Gleevec® (imatinib)

DESCRIPTION

Gleevec is an oral tyrosine kinase inhibitor indicated for the treatment of adult and pediatric chronic myelogenous leukemia in addition to several other malignancies.

APPROVAL DURATION

Approval duration: 1 year

APPROVAL CRITERIA

FDA-Approved Indications

1. Treatment of newly diagnosed adult 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 pediatric patients with Ph+ CML in chronic phase who are newly diagnosed or whose disease has recurred after stem cell transplant or who are resistant to interferon-alpha therapy.
4. Treatment of adult patients with relapsed or refractory Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL).
5. Treatment of adult patients with myelodysplastic or myeloproliferative diseases associated with platelet-derived growth factor receptor gene rearrangements.
6. Treatment of aggressive systemic mastocytosis without the D816V c-Kit mutation or with c-Kit mutational status unknown.
7. Treatment of hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) for patients who have the FIP1L1-PDGFRa fusion kinase and for patients with HES and/or CEL who are FIP1L1-PDGFRa fusion kinase negative or unknown.
8. Treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans.
9. Adjuvant treatment following resection of Kit (CD117) positive gastrointestinal stromal tumors (GIST).
10. Treatment of Kit (CD117) positive unresectable and/or metastatic malignant GIST.

Off-Label Indication(s)

Requests for off-label use of Gleevec will be reviewed and approved when sufficiently supported by evidence from major compendia, published peer-reviewed medical literature, nationally accepted practice guidelines, or expert consensus statements. The major compendia that are recognized include AHFS® Drug Information, Thomson Micromedex®, National Comprehensive Cancer Network Drugs and Biologics Compendium™, and Clinical Pharmacology.