AETNA BETTER HEALTH®
Formulary clinical practice guideline for Gleevec

Authorization guidelines
For patients who have the following:

- Gleevec is prescribed by an oncologist AND
- For the following FDA-approved and NCCN compendium-listed indications
- FDA Approved Indications
  - Newly diagnosed adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase, accelerated phase, or blast phase.
  - Patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase, accelerated phase, or blast phase after failure of a prior therapy (prior interferon-alpha or prior tyrosine kinase inhibitor therapy).
  - 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. There are no controlled trials in pediatric patients demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival.
  - Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL).
  - Pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) in combination with chemotherapy and corticosteroids.
  - Adult patients with myelodysplastic/ myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene rearrangements.
  - Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown.
  - 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.
  - Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP).
  - Patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST).
  - Adjuvant treatment of adult patients following resection of Kit (CD117) positive GIST.
• NCCN listed indications*:
  o Primary treatment for patients with newly diagnosed CML (Philadelphia chromosome or BCR-ABL positive (level of evidence: 1)
  o May be given in combination with chemotherapy for patients presenting with de novo Ph-positive acute lymphocytic leukemia (level of evidence: 2A)
  o Induction or reinduction therapy for Philadelphia chromosome positive stage I-IV disease as a component of HyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose methotrexate and cytarabine) regimen with rituximab in CD20 positive disease (level of evidence: 2A)
  o For Soft tissue sarcoma – Desmoid tumors: Treatment for gross residual disease following surgery or for unresectable disease as an initial treatment or for recurrence (level of evidence: 2A)
  o For bone cancer- chordoma: used as a single-agent therapy or in combination with cisplatin or sirolimus for the treatment of recurrent disease (level of evidence: 2A)
  o Primary treatment for patients with documented GIST (resectable, unresectable, recurrent, or metastatic disease). Imatinib treatment should be continued until disease progression if resection is not feasible. (level of evidence: 2A)

*This list is not inclusive. All off-label use will be reviewed in nationally recognized compendia for the determination of medically-accepted indications.

Authorization and Limitations
• Indications other than GIST, CML, ASM, or HES/CEL: Gleevec will be authorized every year and will be continued as long as there is no evidence of progressive disease or unacceptable toxicity.

• GIST, CML, ASM, or HES/CEL: Gleevec will be authorized every year for patients with GIST, CML, AMS, or HES/CEL. However in presence of disease progression or a demonstrated insufficient response to therapy, a dose increase may be considered in the absence of severe adverse reactions and/or cytopenias.

Additional Information:
Gleevec® is NOT covered for members with the following criteria:
  • Use not approved by the FDA, AND
  • The use is unapproved and not supported by the literature or evidence as an accepted off-label use. (See Off-Label Use Policy for determining ‘accepted use’).
Medically Necessary — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member’s family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

References:

1. Gleevec [full prescribing information]. East Hanover, NJ: Novartis U.S.; Revised 02/2013
2. NCCN Drugs and Biologics Compendium

Last Review: 10/1/2014
PARP Approval: 10/1/2014