Clinical Pharmacy Program Guidelines for Gleevec®

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<th>Program</th>
<th>Prior Authorization</th>
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<td>Medication</td>
<td>Gleevec® (imatinib mesylate)</td>
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<tr>
<td>Pharmacy and Therapeutics</td>
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<td>Effective Date</td>
<td>1/2017</td>
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1. **Background:**

Gleevec® (imatinib mesylate) is a kinase inhibitor indicated for the treatment of:¹

- Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase
- Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase, blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy
- Relapsed or refractory Philadelphia positive acute lymphoblastic leukemia (Ph+ ALL)
- Pediatric patients with newly diagnosed Ph+ ALL in combination with chemotherapy
- Myelodysplastic / myeloproliferative (MDS/MPD) disease associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements
- Aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown
- Hypereosinophilic syndrome (HES) / 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
- Unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP)
- Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST) or adjuvant treatment of adult patients following resection of Kit (CD117) positive GIST

The National Cancer Comprehensive Network (NCCN) also recommends the use of Gleevec for Ph+ acute lymphoblastic lymphoma, desmoid tumors, chordomas, pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT), C-KIT mutated melanoma, and for primary and follow-up chronic myelogenous leukemia (CML) in all phases.²

2. **Coverage Criteria:**
A. Chronic Myelogenous / Myeloid Leukemia

1. Initial Authorization

   a. Gleevec will be approved based on the following criterion:

      (1) Diagnosis of chronic myelogenous / myeloid leukemia (CML)

   Authorization will be issued for 12 months.

2. Reauthorization

   a. Gleevec will be approved based on the following criterion:

      (1) Patient does not show evidence of progressive disease while on Gleevec therapy

   Authorization will be issued for 12 months.

B. Acute Lymphoblastic Leukemia (ALL) / Acute Lymphoblastic Lymphoma

1. Initial Authorization

   a. Gleevec will be approved based on the following criterion:

      (1) Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL) / acute lymphoblastic lymphoma

   Authorization will be issued for 12 months.

2. Reauthorization

   a. Gleevec will be approved based on the following criterion:

      (1) Patient does not show evidence of progressive disease while on Gleevec therapy

   Authorization will be issued for 12 months.

C. Myelodysplastic Disease (MDS) / Myeloproliferative Disease (MPD)

1. Initial Authorization
a. **Gleevec** will be approved based on both of the following criteria:

   (1) Diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD)  
   
   -AND-  

   (2) Disease is associated with platelet-derived growth factor receptor (PDGFR) or PDGFRβ gene re-arrangements

   **Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Gleevec** will be approved based on the following criterion:

   (1) Patient does not show evidence of progressive disease while on Gleevec therapy

   **Authorization will be issued for 12 months.**

D. **Aggressive Systemic Mastocytosis (ASM)**

1. **Initial Authorization**

a. **Gleevec** will be approved based on both of the following criteria:

   (1) Diagnosis of aggressive systemic mastocytosis (ASM)  
   
   -AND-  

   (2) **One** of the following:  
   (a) Patient is without the D816V c-Kit mutation  
   (b) c-Kit mutational status unknown

   **Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Gleevec** will be approved based on the following criterion:

   (1) Patient does not show evidence of progressive disease while on Gleevec therapy
Authorization will be issued for 12 months.

E. **Hypereosinophilic Syndrome (HES) / Chronic Eosinophilic Leukemia (CEL)**

1. **Initial Authorization**
   a. **Gleevec** will be approved based on the following criterion:
      
      (1) Diagnosis of at least one of the following:
      
      (a) Hypereosinophilic syndrome (HES)
      (b) Chronic eosinophilic leukemia (CEL)

      Authorization will be issued for 12 months.

2. **Reauthorization**
   a. **Gleevec** will be approved based on the following criterion:
      
      (1) Patient does not show evidence of progressive disease while on Gleevec therapy

      Authorization will be issued for 12 months.

F. **Dermatofibrosarcoma Protuberans (DFSP)**

1. **Initial Authorization**
   a. **Gleevec** will be approved based on the following criterion:
      
      (1) Diagnosis of dermatofibrosarcoma protuberans (DFSP)

      Authorization will be issued for 12 months.

2. **Reauthorization**
   a. **Gleevec** will be approved based on the following criterion:
      
      (1) Patient does not show evidence of progressive disease while on Gleevec therapy
Authorization will be issued for 12 months.

G. Soft Tissue Sarcoma (off-label)

1. Initial Authorization
   a. Gleevec will be approved based on a diagnosis of one of the following:
      
      (1) Gastrointestinal stromal tumors (GIST)
      (2) Desmoid tumors / aggressive fibromatosis
      (3) Pigmented villonodular synovitis (PVNS) / tenosynovial giant cell tumor (TGCT)

      Authorization will be issued for 12 months.

2. Reauthorization
   a. Gleevec will be approved based on the following criterion:
      
      (1) Patient does not show evidence of progressive disease while on Gleevec therapy

      Authorization will be issued for 12 months.

H. Chordoma (off-label)

1. Initial Authorization
   a. Gleevec will be approved based on the following criterion:
      
      (1) Diagnosis of chordoma

      Authorization will be issued for 12 months.

2. Reauthorization
   a. Gleevec will be approved based on the following criterion:
      
      (1) Patient does not show evidence of progressive disease while on Gleevec therapy

      Authorization will be issued for 12 months.

I. Melanoma (off-label)
1. **Initial Authorization**

   a. **Gleevec** will be approved based on **both** of the following criteria:

      1. Diagnosis of melanoma

      -AND-

      2. Patient has C-KIT mutation

   **Authorization will be issued for 12 months.**

2. **Reauthorization**

   a. **Gleevec** will be approved based on the following criterion:

      1. Patient does not show evidence of progressive disease while on Gleevec therapy

   **Authorization will be issued for 12 months.**

3. **References:**


**HISTORICAL CHANGE NOTES:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Summary of Change</th>
<th>Reason for Change</th>
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<tr>
<td>9/19/2013</td>
<td>New guideline.</td>
<td>Individual guideline created to replace the general Oral Chemotherapy guideline</td>
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<tr>
<td>11/2016</td>
<td>Updated criteria for expanded CML coverage according to NCCN recommendations and simplified formatting of soft tissue sarcoma</td>
<td>Align with NCCN recommendation. Policy template update.</td>
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| | items without change to clinical intent.  
Added “PDGFRß” to Myelodysplastic Disease (MDS) / Myeloproliferative Disease (MPD) section.  
Removed prescriber requirement.  
Added off-label criteria for Chordoma and Melanoma. |