UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Gleevec

Program	Prior Authorization
Medication	Gleevec® (imatinib mesylate)
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

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, or accelerated phase after failure of interferon-alpha therapy
- Relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
- Newly diagnosed Ph+ ALL in combination with chemotherapy
- Myelodysplastic / myeloproliferative (MDS/MPD) diseases associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements as determined with an FDA-approved test
- Aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation as determined with an FDA-approved test or with c-Kit mutational status unknown
- 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
- Unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP)
- Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST)
- Adjuvant treatment of patients following resection of Kit (CD117) positive GIST

The National Cancer Comprehensive Network (NCCN) also recommends the use of Gleevec for 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]

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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)

1. Initial Authorization

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

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

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 (PDGRF) ß 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:

1. Gleevec [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Version 1.2016 Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 6, 2017.

Program	Prior Authorization –Gleevec (imatinib mesylate)
Change Control	
Date	Change
9/19/2013	New guidelines
12/17/2015	Annual Review
11/2016	Updated criteria for expanded CML coverage according to NCCN recommendations and simplified formatting of soft tissue sarcoma 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.
12/2016	Updated background, formatting and references. No changes to clinical intent.
11/2017	Removed acute lymphoblastic lymphoma criteria as no longer recommended by NCCN. Updated references.