UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Gleevec

Program	Prior Authorization
Medication	Gleevec® (imatinib mesylate)
Markets in scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New Mexico, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

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
- Aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation 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 AIDS-related Kaposi sarcoma, 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, steroid-refractory graft-versus-host disease (GVHD), and myeloid/lymphoid neoplasms .[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)

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) **One** of the following:

(a) Disease is associated with 5q32 translocations
(b) Disease is associated with platelet-derived growth factor receptor (PDGRF) ß gene re-arrangements
(c) Disease is associated with a t(5;12) translocation associated with the ETV6-PDGFRβ fusion gene

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
(c) Eosinophilia is present with FIP1L1-PDGFRA fusion gene

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

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

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

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.

J. AIDS-Related Kaposi Sarcoma

1. Initial Authorization

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

(1) Diagnosis of AIDS-related Kaposi Sarcoma

-AND-

(2) Patient is currently being treated with antiretroviral therapy (ART)

-AND-

(3) **Not** used as first line therapy

Authorization will be issued for 12 months.

2. Reauthorization

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

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

Authorization will be issued for 12 months.

K. Steroid-Refractory Chronic Graft-Versus-Host Disease (GVHD)

1. Initial Authorization

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

(1) Diagnosis of chronic graft-versus-host disease

-AND-

(2) Patient is being treated with systemic corticosteroids

-AND-

(3) Patient had no response to first-line therapy options

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.

L. Myeloid/Lymphoid Neoplasms with Eosinophilia

1. **Initial Authorization**

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

(1) Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

-AND-

(2) O**ne** of the following:

(a) FIP1L1-PDGFRA rearrangement

(b) PDGFRB rearrangement

(c) ABL1 rearrangement

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.

M. NCCN Recommended Regimens

1. Initial Authorization

a. **Gleevec** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Gleevec therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Gleevec [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Accessed on September 1, 2020.

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.
9/2018	Added criteria for AIDS-related Kaposi sarcoma and NCCN Recommended Regimens. Updated references.
10/2019	Annual review. Updated references.
10/2020	Annual review. Updated background to reflect PI and NCCN changes and recommendations. Updated clinical criteria to reflect NCCN additions for MDS/MPD and ASM and new recommendations for GVHD and Myeloid/Lymphoid Neoplasms with Eosinophilia. Updated references. Added Additional Clinical Rules section.