UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1037-13
Program	Prior Authorization/Notification
Medication	Gleevec® (imatinib mesylate)
P&T Approval Date	8/2008, 6/2009, 6/2010, 9/2010, 12/2010, 7/2011, 8/2012, 7/2013, 2/2014, 2/2015, 2/2016, 12/2016, 11/2017, 9/2018, 10/2019, 10/2020, 10/2021, 10/2022, 10/2023, 10/2024
Effective Date	1/1/2025

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 diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) 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, for primary and follow-up chronic myelogenous/myeloid leukemia (CML) in all phases, steroid-refractory graft-versus-host disease (GVHD), and myeloid/lymphoid neoplasms[2]

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. 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.

C. 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.

D. 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) Platelet-derived growth factor receptor (PDGFR) 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.

E. 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) KIT D816V mutation negative or unknown
(b) Well-differentiated SM [WDSM]
(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.

F. 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.

G. 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.

H. 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.

I. 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.

J. 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.

K. AIDS-Related Kaposi Sarcoma

1. **Initial Authorization**

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

(1) Diagnosis of AIDS-related Kaposi Sarcoma

-AND-

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

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. 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.

M. 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.

N. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization

management programs may apply

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.
- Please refer to plan specifics to determine exclusion status.

4. References:

1. Gleevec [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on September 4, 2024.

Program	Prior Authorization/Notification - Gleevec (imatinib mesylate)
Change Control	
2/2014	Review with no change to coverage criteria.
2/2015	Annual review with no change to clinical criteria. Updated background and references.
2/2016	Annual Review. Updated background and criteria for expanded CML coverage according to NCCN recommendations and simplified formatting of soft tissue sarcoma items without change to clinical intent.
12/2016	Annual review. Added language to additional clinical rules to "refer to plan specifics to determine exclusion status." Updated background, formatting and references. No changes to clinical intent.
11/2017	Annual review. Removed acute lymphoblastic lymphoma criteria as no longer recommended by NCCN. Updated references.
9/2018	Revised clinical criteria. Added coverage for AIDS-related Kaposi sarcoma. Updated references.
10/2019	Annual review. Added general NCCN recommended review criteria. Updated reference.
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.
10/2021	Annual review with no change to clinical criteria. Reference updated.
10/2022	Annual review with no change to clinical criteria. References updated.

	Added state mandate footnote.
10/2023	Annual review. Updates made o MDS/MPD, ASM, and AIDS-Related Kaposi Sarcoma per NCCN guidelines. Updated reference.
10/2024	Annual review with no change to coverage criteria. Updated references.