MEDICATION POLICY

Generic Name: Imatinib

Therapeutic Class or Brand Name: Gleevec®

Applicable Drugs (if Therapeutic Class)**:**

Preferred: Imatinib tablets (generic)

Non-Preferred: Gleevec® tablets

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 9/29/16

GPI Code: 2153403510

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):

I. Documented diagnosis of one of the following conditions A through G AND must meet criteria listed under applicable diagnosis:

A. Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML) and criterion 1 is met:

1. Minimum age requirement: 1 year old.

B. Gastrointestinal stromal tumor (GIST) and criterion 1 is met:

1. Minimum age requirement: 18 years old.

C. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) or lymphoma and criterion 1 is met:

1. Minimum age requirement: 1 year old.

D. Myelodysplastic/ myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements and criterion 1 is met:

1. Minimum age requirement: 18 years old.

E. Aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown and criterion 1 is met:

1. Minimum age requirement: 18 years old.

F. Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) in patients 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 and criterion 1 is met:

1. Minimum age requirement: 18 years old.

G. Unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP) and criterion 1 is met:

1. Minimum age requirement: 18 years old.

II. The prescribing physician is an oncologist or a hematologist.

III. Non-preferred products (i.e. Gleevec® tablets) require a documented clinical reason containing details as to why generic imatinib is not appropriate or is contraindicated.

Exclusion Criteria:

- N/A

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Doses are limited to 800 mg per day. The quantity is limited to a maximum of a 30 day supply per fill.

Approval Length:

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix:

N/A

References:

1. http://blue.regence.com/trgmedpol/drugs/dru043.pdf.
2. Medi-Span.
3. http://www.pharma.us.novartis.com/product/pi/pdf/gleevec_tabs.pdf.
4. https://www.nccn.org/professionals/physician_gls/pdf/nhl.pdf.

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5. https://www.nccn.org/professionals/physician_gls/pdf/all.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
9/29/2016	1. **Changed** "N/A" **to** "Preferred: Imatinib tablets (generic); Non-Preferred: Gleevec® tablets" **following Applicable Drugs**. 2. **Changed** "I. C. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) and criterion 1 is met…" **to** "I. C. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) or lymphoma and criterion 1 is met…" **under Prior Authorization Criteria**. 3. **Added** "III. Non-preferred products (i.e. Gleevec® tablets) require a documented clinical reason containing details as to why generic imatinib is not appropriate or is contraindicated" **under Prior Authorization Criteria**. 4. **Added** "https://www.nccn.org/professionals/physician_gls/pdf/nhl.pdf" **and** "https://www.nccn.org/professionals/physician_gls/pdf/all.pdf" **under References**.
3/28/2015	1. Policy reviewed: no changes made.
11/22/2013	1. **Adapted policy to new format.** 2. **Added GPI Code**. 3. **Changed** "Chronic myelogenous leukemia (CML) with the presence of the Philadelphia (Ph-1) chromosome" **to** "Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML)" **under Prior Authorization Criteria**. 4. **Added minimum age requirements to all diagnoses listed under Prior Authorization Criteria**. 5. **Added** "The prescribing physician is an oncologist or a hematologist" **under Prior Authorization Criteria**. 6. **Changed Quantity/Days Supply Restrictions from** "Authorized in quantities of up to 800 mg per day" **to** "Doses are limited to 800 mg per day. The quantity is limited to a maximum of a 30 day supply per fill". 7. **Updated references** to include Medi-Span and Gleevec package insert.