STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMATINIB MESYLATE	GLEEVEC, IMATINIB MESYLATE	22096		GPI-10 (2153183510)	

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Newly diagnosed Philadelphia positive chronic myeloid leukemia (Ph+ CML) in chronic phase
   - Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient received previous treatment with another tyrosine kinase inhibitor [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)]?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #2 per day.**
   - **Gleevec 100mg: #6 per day.**

3. Does the patient have a diagnosis of relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #1 per day.**
   - **Gleevec 100mg: #6 per day.**

   If no, continue to #4.

CONTINUED ON NEXT PAGE

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) **AND** meet the following criterion?
   - The requested medication will be used in combination with chemotherapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #1 per day.**
   - **Gleevec 100mg: #6 per day.**

   If no, continue to #5.

5. Does the patient have a diagnosis of a myelodysplastic/myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve Gleevec 400mg for 12 months by GPID or GPI-14 with a quantity limit of #1 tablet per day.**
   If no, continue to #6.

6. Does the patient have a diagnosis of aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #1 per day.**
   - **Gleevec 100mg: #3 per day.**

   If no, continue to #7.

7. Does the patient have a diagnosis of hypereosinophilic syndrome and/or chronic eosinophilic leukemia **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #1 per day.**
   - **Gleevec 100mg: #3 per day.**

   If no, continue to #8.

CONTINUED ON NEXT PAGE

IMATINIB

GUIDELINES FOR USE (CONTINUED)

8. Does the patient have a diagnosis of unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #2 per day.**
   - **Gleevec 100mg: #6 per day.**

   If no, continue to #9.

9. Does the patient have a diagnosis of unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST) with a Kit (CD117) positive?

   If yes, continue to #11.
   If no, continue to #10.

10. Is the request for adjuvant treatment following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumor (GIST) **AND** the patient meets the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

11. Is the request for Gleevec 400mg twice daily?

    If yes, continue to #12.
    If no, **approve as follows:**
    - **For adjuvant GIST treatment: approve Gleevec 400mg for 36 months by GPID or GPI-14 with a quantity limit of #1 per day.**
    - **For unresectable and/or metastatic malignant GIST: approve Gleevec 400mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**

CONTINUED ON NEXT PAGE

IMATINIB

GUIDELINES FOR USE (CONTINUED)

12. Has patient tried Gleevec 400mg once daily or does the patient have GIST tumor expressing a KIT exon 9 mutation?

    If yes, **approve as follows:**
    - **For adjuvant GIST treatment: approve Gleevec 400mg for 36 months by GPID or GPI-14 with a quantity limit of #2 per day.**
    - **For unresectable and/or metastatic malignant GIST: approve Gleevec 400mg for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, do not approve.
    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **IMATINIB (Gleevec)** requires the following rule(s) be met for approval:
    A. You have ONE of the following diagnoses:
        1. Newly diagnosed Philadelphia positive chronic myeloid leukemia (type of blood cell cancer that begins in bone marrow with an abnormal gene) in chronic phase
        2. Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy
        3. Relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer that has returned or did not respond to treatment)
        4. Newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)
        5. Myelodysplastic/myeloproliferative disease (a group of diseases where the bone marrow makes too many white blood cells) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements
        6. Aggressive systemic mastocytosis (a type of cell accumulates in internal tissues and organs) without D816V c-Kit mutation or with c-Kit mutational status unknown
        7. Hypereosinophilic syndrome and/or chronic eosinophilic leukemia (type of inflammatory cancer)
        8. Unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (type of rare skin tumor that cannot be completely removed by surgery or returns/ spreads)
        9. Unresectable and/or metastatic malignant gastrointestinal stromal tumor (tumor in stomach/intestines that spreads or cannot be removed by surgery) with a Kit (CD117) positive
        10. Adjuvant (add-on) treatment after complete gross resection (surgical removal) of Kit (CD117) positive gastrointestinal stromal tumor

    (Denial text continued on next page)

CONTINUED ON NEXT PAGE

IMATINIB

GUIDELINES FOR USE (CONTINUED)

B. **If you are newly diagnosed with Philadelphia positive chronic myeloid leukemia in chronic phase, approval also requires:**
   1. You have NOT received previous treatment with another tyrosine kinase inhibitor such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)

C. **If you have Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy, approval also requires:**
   1. You have NOT received previous treatment with another tyrosine kinase inhibitor such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)

D. **If you have relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. You are 18 years of age or older

E. **If you have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. The requested medication will be used in combination with chemotherapy

F. **If you have myelodysplastic/myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements, approval also requires:**
   1. You are 18 years of age or older

G. **If you have aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown, approval also requires:**
   1. You are 18 years of age or older

H. **If you have hypereosinophilic syndrome and/or chronic eosinophilic leukemia, approval also requires:**
   1. You are 18 years of age or older

I. **If you have unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans, approval also requires:**
   1. You are 18 years of age or older

J. **If the request is for adjuvant treatment following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumor (GIST), approval also requires:**
   1. You are 18 years of age or older

K. **If you have gastrointestinal stromal tumor, approval also requires:**
   1. For request of Gleevec 400mg twice daily, approval requires a trial of Gleevec 400mg once daily OR a GIST tumor expressing a KIT exon 9 (type of gene) mutation (a permanent change in your DNA that make up your gene)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

IMATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gleevec.

REFERENCES

- Gleevec [Prescribing Information] East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 11/11
Client Approval: 03/21
P&T Approval: 10/19