IMATINIB

Generic	Brand	HICL	GCN	Exception/Other
IMATINIB MESYLATE	GLEEVEC	22096		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of **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 with a quantity limit of #1 tablet per day for Gleevec 400mg and #2 tablets per day for Gleevec 100mg (enter two authorizations).**

3. Does the patient have a diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)?

   If yes, **approve for 12 months by GPID with a quantity limit of #1 tablet per day for Gleevec 400mg and #2 tablets per day for Gleevec 100mg (enter two authorizations).**
   If no, continue to #4.

4. Does the patient have a diagnosis of a myelodysplastic/myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements?

   If yes, **approve for 12 months by GPID with a quantity limit of #1 tablet per day for Gleevec 400mg.**
   If no, continue to #5.

5. Does the patient have a diagnosis of aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown?

   If yes, **approve for 12 months by GPID with a quantity limit of #1 tablet per day for Gleevec 400mg and #3 tablets per day for Gleevec 100mg (enter two authorizations).**
   If no, continue to #6.

CONTINUED ON NEXT PAGE

IMATINIB

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of hypereosinophilic syndrome and/or chronic eosinophilic leukemia?

   If yes, **approve for 12 months by GPID with a quantity limit of #1 tablet per day for Gleevec 400mg and #3 tablets per day for Gleevec 100mg (enter two authorizations).**
   If no, continue to #7.

7. Does the patient have a diagnosis of unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans?

   If yes, **approve for 12 months by GPID with a quantity limit of #2 tablets per day for both Gleevec 100mg and 400mg (enter two authorizations).**
   If no, continue to #8.

8. 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 #10.
   If no, continue to #9.

9. Is the request for adjuvant treatment following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumor (GIST)?

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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

    If yes, continue to #11.
    If no, **approve as follows:**
    - **For adjuvant GIST treatment: approve for 36 months by GPID with a quantity limit of #1 tablet per day for Gleevec 400mg.**
    - **For unresectable and/or metastatic malignant GIST: approve for 12 months by GPID with a quantity limit of #1 tablet per day for Gleevec 400mg.**

CONTINUED ON NEXT PAGE

IMATINIB

GUIDELINES FOR USE (CONTINUED)

11. 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 for 36 months by GPID with a quantity limit of #2 tablets per day for Gleevec 400mg.**
    - **For unresectable and/or metastatic malignant GIST: approve for 12 months by GPID with a quantity limit of #2 tablets per day for Gleevec 400mg.**

    If no, do not approve.
    DENIAL TEXT: The guideline named **IMATINIB (Gleevec)** requires a diagnosis of 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; Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL); myelodysplastic/myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements; aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown; hypereosinophilic syndrome and/or chronic eosinophilic leukemia; unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans; unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST) with a Kit (CD117) positive; or adjuvant treatment following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumor (GIST). In addition, the following must be met:
    For newly diagnosed Philadelphia positive chronic myeloid leukemia (Ph+ CML) in chronic phase OR Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis, accelerated phase, or chronic phase, approval requires:
    - The patient has NOT received previous treatment with another tyrosine kinase inhibitor [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)]

    For the treatment of gastrointestinal stromal tumor (GIST), approval requires:
    - 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 mutation

---

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: 01/01/20
Created: 11/11
Client Approval: 11/19
P&T Approval: 10/19