RxAdvance

Clinical Policy Title:	imatinib mesylate
Policy Number:	RxA.788
Drug(s) Applied:	imatinib mesylate
Original Policy Date:	04/13/2023
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. **Initial Approval Criteria**
  A. **FDA Labelled Indications** (must meet all):
    1. Diagnosis of one of the following:
      a. Newly diagnosed Philadelphia chromosome positive (Ph+/BCR-ABL+) chronic myeloid leukemia in chronic phase;
      b. Philadelphia chromosome positive (Ph+/BCR-ABL+) chronic myeloid leukemia in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy;
      c. Relapsed or refractory Philadelphia chromosome (Ph+/BCR-ABL+) acute lymphoblastic leukemia;
      d. Newly diagnosed Philadelphia chromosome (Ph+/BCR-ABL+) acute lymphoblastic leukemia in combination with chemotherapy;
      e. Myelodysplastic/myeloproliferative diseaseassociated platelet-derived growth factor receptor gene arrangements;
      f. Aggressive systemic mastocytosiswithouthe D816V c-Kit mutation or with unknown c-Kit mutation status;
      g. Hypereosinophilic syndrome or chronic eosinophilic leukemia with FIP1L1-PDGFRα fusion kinase or with unknown mutation status;
      h. Unresectable, recurrent, or metastatic dermatofibrosarcoma protuberans;
      i. Kit (CD117) positve unresectable or metastatic malignant gastrointestinal tromal tumors (GIST);
      j. Adjuvant treatment following resection of Kit (CD117) positive GIST.

  Initial Approval Duration
  All Lines of Business (except Medicare): 12 months

II. **Continued Therapy Approval**
  A. **All Indications in Section I** (must meet all):
    1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

  Approval Duration
  All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network Guidelines. Chronic Myeloid Leukemia. Version 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed March 25, 2025.
2. National Comprehensive Cancer Network Guidelines. Pediatric Acute Lymphoblastic Leukemia. Version 3.2025.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed March 25, 2025.
3. National Comprehensive Cancer Network Guidelines. Gastrointestinal Stromal Tumors (GISTs). Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf. Accessed March 25, 2025.
4. National Comprehensive Cancer Network Guidelines. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed March 25, 2025.
5. National Comprehensive Cancer Network Guidelines. Dermatofibrosarcoma Protuberans Version 5.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed March 25, 2025.
6. National Comprehensive Cancer Network Guidelines. Hematopoietic Cell Transplantation Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed March 25, 2025.
7. National Comprehensive Cancer Network Guidelines. Kaposi Sarcoma Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kaposi.pdf. Accessed March 25, 2025.
8. National Comprehensive Cancer Network Guidelines. Melanoma: Cutaneous Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed March 25, 2025.
9. National Comprehensive Cancer Network Guidelines. Soft Tissue Sarcoma Version.5.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed March 25, 2025.
10. National Comprehensive Cancer Network Guidelines. Systemic Mastocytosis Version. 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis.pdf. Accessed March 25, 2025.
11. National Comprehensive Cancer Network Guidelines. Myelodysplastic Syndromes Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed March 25, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/30/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. I.A.3: Removed age criteria 2. Removed all off-label dosing criteria. 3. Revised indication criteria 4. Updated initial therapy approval to 12 monthsII.A: Revised statement for continued therapy approval and removed dosing 5. Removed Prescriber restrictions	04/03/2024	
Policy was reviewed: 1. Removed brand name from drug applied section. 2. Updated continuation of therapy language. 3. References were reviewed and updated.	03/25/2025	04/10/2025
Policy reviewed.	12/11/2025	12/11/2025

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