Clinical Policy Title:	imatinib mesylate
Policy Number:	RxA.788
Drug(s) Applied:	Gleevec®
Original Policy Date:	04/13/2023
Last Review Date:	10/19/2023
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. Ph+ (BCR-ABL1-positive) CML or Ph+ (BCR-ABL-positive) ALL;
   b. MDS/MPD and member meets one of the following (i ii or iii):
      i. Disease is positive for a PDGFR mutation;
      ii. Disease is associated with a t(5;12) translocation associated with the ETV6-PDGFRβ fusion gene;
      iii. Disease is associated with PDGFRβ gene rearrangements at 5q32;
   c. ASM and member meets one of the following (i - iv):
      i. Disease is negative for the D816V c-KIT mutation;
      ii. c-Kit mutational status is unknown;
      iii. Well-differentiated systemic mastocytosis;
      iv. Eosinophilia is present with FIP1L1-PDGFRA fusion gene;
   d. HES/CEL, DFSP, or GIST (a soft tissue sarcoma);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years if the diagnosis is MDS/MPD, ASM, HES/CEL, DFSP, or GIST;
4. Request meets one of the following (a or b):*
   a. Dose does not exceed any of the following (i, ii, or iii):
      i. 800 mg per day: CML, DFSP, GIST;
      ii. 600 mg per day: ALL;
      iii. 400 mg per day: MDS/MPD, ASM, HES/CEL;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
      *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 6 months
Medicaid: 6 months

B. NCCN Recommended Off-Label Indications (must meet all):

1. Diagnosis of one of the following:
   a. Kaposi sarcoma (KS), and both of the following (i and ii):
      i. If request is for AIDS-related KS, imatinib is prescribed in combination with antiretroviral

therapy;
   ii. Trial and failure of liposomal doxorubicin and paclitaxel, unless clinically significant adverse effects are experienced or both are contraindicated;
b. Recurrent conventional or chondroid chordoma (a bone cancer);
c. KIT-positive metastatic or unresectable melanoma as second-line or subsequent therapy;
d. Desmoid tumor (also known as aggressive fibromatosis, a soft tissue sarcoma);
e. Myeloid/lymphoid neoplasm with eosinophilia and tyrosine kinase fusion genes;
f. Pigmented villonodular synovitis/tenosynovial giant cell tumor PVNS/TGCT (a soft tissue sarcoma) as single-agent therapy;
g. Chronic graft-versus-host disease - as additional therapy in conjunction with systemic corticosteroids following no response (steroid-refractory disease) to first-line therapy options;

2. Prescribed by or in consultation with one of the following specialists (a or b):
   a. AIDS-related KS: an oncologist or immunologist;
   b. All other diagnoses: an oncologist;
3. Age ≥ 18 years;
4. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):
1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria for the covered indications and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed any of the following (i, ii, or iii):
      i. 800 mg per day: CML, DFSP, GIST;
      ii. 600 mg per day: ALL;
      iii. 400 mg per day: MDS/MPD, ASM, HES/CEL;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
      *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network Guidelines. Chronic Myeloid Leukemia. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed January 30, 2023.
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5. National Comprehensive Cancer Network Guidelines. Dermatofibrosarcoma Protuberans Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed January 30, 2023.
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9. National Comprehensive Cancer Network Guidelines. Soft Tissue Sarcoma Version. 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed January 30, 2023.
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11. National Comprehensive Cancer Network Guidelines. Myelodysplastic Syndromes Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed January 30, 2023.

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