Gleevec (imatinib mesylate)

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient’s benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. Please respond below and fax this form to CVS Caremark toll-free at 1-866-249-6155. If you have questions regarding the prior authorization, please contact CVS Caremark at 1-866-814-5506. For inquiries or questions related to the patient’s eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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Page 1 of 4
5. Has the patient experienced a documented intolerable adverse event to imatinib (generic)?  
ACTION REQUIRED: If Yes, attach supporting chart note(s).  
☐ Yes  ☐ No  If No, complete this form in its entirety and State Step Therapy section.

6. Was the intolerable adverse event an expected adverse event attributed to the active ingredient (i.e., imatinib) as described in the prescribing information?  
ACTION REQUIRED: If No, attach supporting chart note(s).  
☐ Yes  ☐ No  If No, complete this form in its entirety and State Step Therapy section.

7. Does the patient have a diagnosis of either of the following?  
☐ Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)  
☐ Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL)  
☐ None of the above, skip to diagnosis section

8. If Ph+ CML, has the patient had a documented inadequate response, resistance, or intolerable adverse event to treatment with both of the other preferred products: Bosulif and Sprycel?  
ACTION REQUIRED: If Yes, attach supporting chart note(s).  
☐ Yes  ☐ No  If No, complete this form in its entirety and State Step Therapy section.

9. If Ph+ ALL, has the patient had a documented inadequate response, resistance, or intolerable adverse event to treatment with the other preferred product Sprycel?  
ACTION REQUIRED: If Yes, attach supporting chart note(s).  
☐ Yes  ☐ No  If No, complete this form in its entirety and State Step Therapy section.

Complete the following section based on patient's diagnosis, if applicable.

Section A: Hypereosinophilic Syndrome (HES)/Chronic Eosinophilic, Leukemia (CEL), Desmoid Tumors,  
Dermatofibrosarcoma Protuberans (DFSP), Pigmented Villonodular, Synovitis (PVNS)/Tenosynovial Giant Cell Tumor (TGCT)

10. Is the patient currently receiving the requested medication?  
☐ Yes  ☐ No  If No, no further questions.

11. Is there any evidence of disease progression or unacceptable toxicity?  
☐ Yes  ☐ No

Section B: Chronic Myeloid Leukemia (CML)

12. Was the diagnosis confirmed by detection of Philadelphia (Ph) chromosome or BCR-ABL gene by cytogenetic (conventional or FISH) and/or molecular (PCR) testing?  
ACTION REQUIRED: If Yes, attach cytogenetic and/or molecular test results.  
☐ Yes  ☐ No

13. Is the patient currently receiving the requested medication?  
If Yes, skip to #15  ☐ Yes  ☐ No

14. Did the patient fail (not due to intolerance) prior therapy with a tyrosine kinase inhibitor (TKI) (e.g., bosutinib [Bosulif®], nilotinib [Tasigna®], dasatinib [Sprycel®], or ponatinib [Iclusig®])?  
☐ Yes  ☐ No  If No, no further questions

15. Has the patient received a hematopoietic stem cell transplant (HSCT) for CML?  
If Yes, skip to #18  ☐ Yes  ☐ No

16. How many months of treatment has the patient received with the requested medication?  
______________ months  
If greater than 12 months, skip to #18

17. What is the most recent BCR-ABL1 (IS) level (%)?  
______________  ☐ Unknown  If No, no further questions

18. Is there evidence of unacceptable toxicity or disease progression on the current regimen?  
☐ Yes  ☐ No

Section C: Acute Lymphoblastic Leukemia (ALL)/Lymphoblastic Lymphoma (LL)

19. What is the ALL/LL subtype?  
☐ Philadelphia (Ph) chromosome positive ALL/LL  
☐ T-cell ALL/LL with ABL-class translocation, skip to #21  
☐ Other ____________________________

20. Was the diagnosis confirmed by detection of Philadelphia (Ph) chromosome or BCR-ABL gene by cytogenetic (conventional or FISH) and/or molecular (PCR) testing?  
ACTION REQUIRED: If Yes, attach results of cytogenetic and/or molecular testing.  
☐ Yes  ☐ No  If No, no further questions

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Page 2 of 4
21. Was the ABL-class translocation confirmed by cytogenetic (conventional or FISH) and/or molecular (PCR) testing?  **ACTION REQUIRED: If Yes, attach results of cytogenetic and/or molecular testing.**  ☐ Yes ☐ No

22. Is the patient currently receiving the requested medication?  **If Yes, skip to #45**  ☐ Yes ☐ No

23. Is the patient’s disease relapsed or refractory?  ☐ Yes ☐ No

Section D: Myelodysplastic Syndromes (MDS)/Myeloproliferative Diseases (MPD)/Chronic Myelomonocytic Leukemia (CMML)
24. Is the patient currently receiving the requested medication?  **If Yes, skip to #45**  ☐ Yes ☐ No

25. Is the condition associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements?  ☐ Yes ☐ No

Section E: Aggressive Systemic Mastocytosis (ASM)
26. Is the patient currently receiving the requested medication?  **If Yes, skip to #45**  ☐ Yes ☐ No

27. Is eosinophilia present with FIP1L1-PDGFR fusion gene?  **If Yes, no further questions**  ☐ Yes ☐ No

28. Is the patient positive for the D816V c-KIT mutation?  ☐ Yes ☐ No ☐ Unknown

Section F: Melanoma
29. Is the disease metastatic or unresectable?  ☐ Yes ☐ No

30. Is the patient currently receiving the requested medication?  **If Yes, skip to #45**  ☐ Yes ☐ No

31. Is the patient positive for the c-KIT mutation?  ☐ Yes ☐ No

32. Will the requested medication be used as second-line or subsequent therapy?  ☐ Yes ☐ No

33. Will the requested medication be used as a single agent?  ☐ Yes ☐ No

Section G: Chordoma
34. Is the disease recurrent?  ☐ Yes ☐ No

35. Is the patient currently receiving the requested medication?  **If Yes, skip to #45**  ☐ Yes ☐ No

Section H: AIDS-Related Kaposi Sarcoma
36. Is the patient currently receiving the requested medication?  **If Yes, skip to #45**  ☐ Yes ☐ No

37. Will the requested medication be used as subsequent therapy?  ☐ Yes ☐ No

38. Will the requested medication be used in combination with antiretroviral therapy?  ☐ Yes ☐ No

Section I: Chronic Graft Versus Host Disease (cGVHD)
39. Is the patient currently receiving the requested medication?  **If Yes, skip to #45**  ☐ Yes ☐ No

40. Will the requested medication be used as subsequent therapy?  ☐ Yes ☐ No

41. Will the requested medication be used in combination with systemic corticosteroids?  ☐ Yes ☐ No

Section J: Myeloid/Lymphoid Neoplasms with Eosinophilia
42. Is the patient currently receiving the requested medication?  **If Yes, skip to #45**  ☐ Yes ☐ No

43. Does the disease have ABL1, FIP1L1-PDGFR, or PDGFRB rearrangement?  **ACTION REQUIRED: If Yes, attach results of testing or analysis confirming ABL1, FIP1L1-PDGFR, or PDGFRB rearrangement.**  ☐ Yes ☐ No ☐ Unknown or testing has not been completed

44. Is the disease in chronic or blast phase?  ☐ Yes - Chronic phase ☐ Yes - Blast phase ☐ No

Section K: Continuation of Therapy - All Other Diagnoses
45. Is there evidence of unacceptable toxicity or disease progression on the current regimen?  ☐ Yes ☐ No

**Section L: Gastrointestinal Stromal tumor (GIST).**

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Page 3 of 4
46. Is the patient currently receiving the requested medication?  □ Yes  □ No  If No, no further questions.

47. Is the patient receiving clinical benefit and have no evidence of unacceptable toxicity while on the current regimen?  □ Yes  □ No

State Step Therapy
1. Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?  □ Yes  □ No

2. Does the prescribed quantity fall within the manufacturer’s published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?  □ Yes  □ No

3. Does the patient reside in Maryland?  □ Yes  □ No  If No, skip to #7

4. Is the alternate drug (generic imatinib, Bosulif, and Sprycel) FDA-approved for the medical condition being treated?  □ Yes  □ No  If No, please specify: ________________________________

5. Has the prescriber provided proof, documented in the patient’s chart notes, indicating that the requested drug was ordered for the patient in the past 180 days?  □ Yes  □ No  If No, skip to #7

6. Has the prescriber provided proof, documented in the patient chart notes, that in their opinion the requested drug is effective for the patient’s condition?  □ Yes  □ No  No further questions

7. Are any of the following conditions met for the alternate drug (generic imatinib, Bosulif, and Sprycel)?  □ The alternate drug is contraindicated
 □ The alternate drug is likely to cause an adverse reaction, physical or mental harm
 □ The alternate drug is expected to be ineffective
 □ The alternate drug was previously tried or a drug in the same class or with the same action was previously tried and was stopped due to ineffectiveness or an adverse event
 □ The alternate drug is not in the patient’s best interest
 □ The alternate drug was tried while covered by the current or the previous health benefit plan
 □ None of the above

   If Yes, please specify: ________________________________

8. Is the patient stable or currently receiving a positive therapeutic outcome with the requested drug and a change in the prescription drug is expected to be ineffective or cause harm to the patient?  □ Yes  □ No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X ____________________________  ____________________________
Prescriber or Authorized Signature  Date (mm/dd/yy)