

CRITERIA FOR APPROVAL

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| <p>1. Does the patient have any of the following diagnoses?</p> <ul style="list-style-type: none"> • Newly Diagnosed Philadelphia Positive Chronic Myeloid Leukemia (Ph+ CML) • Ph+ CML in Blast Crisis (BC), Accelerated Phase (AP) or Chronic Phase (CP) After Interferon-alpha (IFN) Therapy • Pediatric Patients with Ph+ CML in Chronic Phase (Pediatric patients with Ph+ CML in chronic phase who are newly diagnosed or whose disease has recurred after stem cell transplant or who are resistant to interferon-alpha therapy. • Ph+ Acute Lymphoblastic Leukemia (ALL) (Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia) • Myelodysplastic/Myeloproliferative Diseases (MDS/MPD) • Aggressive Systemic Mastocytosis (ASM) • Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL) • Dermatofibrosarcoma Protuberans (DFSP) • Kit+ Gastrointestinal Stromal Tumors (GIST) • Aggressive fibromatosis <p>[If the answer to this question is no, then no further questions are required.]</p> | Yes | No |
| <p>2. Will the prescribed amount exceed either of the following dosage unit strength-specific quantities?</p> <ul style="list-style-type: none"> • Gleevec 100mg tablets: #270 tablets / 90 days • Gleevec 400mg tablets: #180 tablets / 90 days <p>[If the answer to this question is yes, then no further questions are required.]</p> | Yes | No |
| <p>3. If applicable, are the physician and patient aware that this drug must not be taken if the patient is pregnant or may become pregnant?</p> | Yes | No |

Guidelines for Approval

Duration of Approval		6 Months
Set 1		
YES to question(s)	NO to question(s)	
1	2	
3		

Horizon BCBSNJ Pharmacy Guideline Development Process: This Horizon BCBSNJ Pharmacy Guideline (the “Pharmacy Guideline”) has been developed by Horizon BCBSNJ’s Pharmacy Drug Policy Subcommittee, Clinical Issues Subcommittee, and Quality Improvement Committee which include practicing physicians and pharmacists. This guideline is consistent with generally accepted standards of medical and pharmacy practice, and reflects Horizon BCBSNJ’s view of the subject health care services, supplies drugs or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational in nature. This Pharmacy Guideline also considers whether and to what degree the subject health care services, supplies or procedures are clinically appropriate, in terms of type, frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Pharmacy Guideline considers whether the subject prescription drugs are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the prescription drugs are more costly than alternative prescription drugs that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical and pharmacy practice, Horizon BCBSNJ reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing

opinion within the appropriate specialty), the findings and directives of the Food and Drug Administration and any other relevant factor as determined by applicable State and Federal laws and regulations.

RATIONALE

The intent of the criteria is to ensure that patients follow selection elements established by Horizon BCBS New Jersey's medical policies.

REFERENCES

1. Gleevec product information. Novartis Pharmaceuticals Corporation. November 2006.
2. Faderl S, Talpaz M, Estrov Z, et al. The biology of chronic myeloid leukemia. *N Engl J Med.* 1999 Jul 15;341(3):164-72.
3. Kantarjian HM, O'Brien S, Cortes JE, et al. Imatinib mesylate therapy for relapse after allogeneic stem cell transplantation for chronic myelogenous leukemia. *Blood.* 2002 Sep 1;100(5):1590-95.
4. Kantarjian H, Sawyers C, Hochhaus A, et al. Hematologic and cytogenetic responses to imatinib mesylate in chronic myelogenous leukemia. *N Engl J Med.* 2002 Feb 28;346(9):645-52.
5. Talpaz M, Silver RT, Druker BJ, et al. Imatinib induces durable hematologic and cytogenetic responses in patients with accelerated phase chronic myeloid leukemia: results of a phase 2 study. *Blood.* 2002 Mar 15;99(6):1928-37.
6. USPDI. Thomson MICROMEDEX. 2007.
7. American Hospital Formulary Service. American Society of Health-System Pharmacists. 2007.
8. MICROMEDEX Thomson Healthcare. MICROMEDEX Inc. Greenwood Village, CO. April 2007.

Pharmacy Guidelines can be highly technical and are designed for use by the Horizon BCBSNJ professional staff in making coverage determinations. Members referring to this policy should discuss it with their treating physician or pharmacist, and should refer to their specific benefit plan for the terms, conditions, limitations and exclusions of their coverage.

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