

**Blue Cross Blue Shield of Vermont and The Vermont Health Plan
Prior Authorization Guidelines
Gleevec® (imatinib mesylate)**

Description: Imatinib mesylate is a protein-tyrosine kinase inhibitor that blocks Bcr-Abl tyrosine kinase, the product of the Philadelphia chromosome in chronic myeloid leukemia (CML). Imatinib inhibits proliferation and induces apoptosis in Bcr-Abl positive cell lines and fresh leukemic cells from Philadelphia CML. Imatinib also inhibits tyrosine kinase for platelet-derived growth factor (PDGF), stem cell factor (SCF), c-kit, and PDGF and SCF-mediated cellular events.

Indications: Imatinib is indicated for treatment of patients with chronic myeloid leukemia (CML) in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy, or newly diagnosed patients. It is also used in patients with Kit (CD117) positive unresectable and/or metastatic malignant GI stromal tumors. Also, Imatinib is used to treat dermatofibrosarcoma protuberans tumors, as well as the following blood diseases: Philadelphia chromosome-positive acute lymphoblastic leukemia, hypereosinophilic syndrome, aggressive systemic mastocytosis, and some forms of myeloproliferative disorders.

**Warnings/
Precautions:** Consider drug interactions with concomitant drugs that alter cytochrome P450 activity. Imatinib can cause GI irritation, hepatotoxicity, or hematologic toxicity (neutropenia or thrombocytopenia). Use with caution in patients with cardiovascular or pulmonary disease or any condition where fluid retention is a potential side effect.

Reasons for Prior Authorization: Cost Potential for misuse Toxicity

Criteria for Approval: 1) Diagnosis is an FDA-Labeled Indication **and**
2) Patient has no contraindications to treatment (See Below) **and**

Reasons for Denial of Benefit: 1) Patient has the following **contraindications**
a) History of hypersensitivity to imatinib or its components.
b) Pregnancy.
2) Patient does not meet criteria

Benefit Approval Initial approval for 3 month period; Renewal approval period 6 months;
Allow only for 30 days supplies.

References:

1. Lacy, CF, Armstrong, LL, Goldman, MP et al. Imatinib mesylate. Drug information Handbook. Lexi-Comp Inc. Hudson, 2002-2003, p.703-5.
2. Olin BR, ed. Imatinib mesylate. Protein-tyrosine kinase inhibitors. Drug Facts and Comparisons (Updated monthly). St. Louis, May, 2003.
3. Gleevec® prescribing information, Novartis Pharmaceuticals Corporation. East Hanover, NJ 2003.