

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____
Pharmacy Phone: _____

Complete the Clinical Assessment:

STEP
2

Diagnosis	Philadelphia+ Chronic Myeloid Leukemia (CML) (with one of the following): <input type="checkbox"/> Adults newly diagnosed in Chronic Phase <input type="checkbox"/> Blast Crisis, Accelerated Phase, or in Chronic Phase after failure of interferon-alpha tx <input type="checkbox"/> Pediatrics newly diagnosed in Chronic Phase or have reoccurrence after stem cell transplant or failure with interferon-alpha tx	<input type="checkbox"/> Aggressive Systemic Mastocytosis (ASM) without expression of c-KIT mutation or c-KIT mutation unknown
	<input type="checkbox"/> Ph+ Acute Lymphoblastic Leukemia (ALL)	<input type="checkbox"/> Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)
	<input type="checkbox"/> Gastrointestinal stromal tumor (GIST) expressing c-KIT protein either as treatment or prophylaxis post surgery.	<input type="checkbox"/> Unresectable Dermatofibrosarcoma Protuberans (DFSP)
	<input type="checkbox"/> Myelodysplastic/Myeloproliferative Diseases (MDS/MPD) assoc. with Platelet Derived Growth Factor Receptor	<input type="checkbox"/> Other (please state):
Physician Specialty	<input type="checkbox"/> Oncology	<input type="checkbox"/> Other (please state):
Supporting Documentation	Diagnosis: ICD-9 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Gleevec® (imatinib mesylate) Strength _____ Sig _____ Qty _____ Refills _____	
	Please attach all relevant medical records and test results. Incomplete forms will not be processed.	

I certify that the above is correct and accurate to the best of my knowledge (please sign and date).

STEP
3

Prescriber Signature

Date

STEP
4

Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:

970-248-5034

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options.

04/29/11

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Gleevec (imatinib)

CLASSIFICATION

- Antineoplastic, tyrosine kinase inhibitor

DESCRIPTION

- Imatinib mesylate is a protein-tyrosine kinase inhibitor that is indicated for the treatment of Philadelphia chromosome positive chronic myeloid leukemia (CML). It suppresses the proliferation and promotes apoptosis in bcr-abl positive cell lines and fresh leukemic cells
- Imatinib is a phenylaminopyrimidine derivative and a selective inhibitor of the tyrosine kinase activity of BCR-ABL fusion gene (oncoprotein), the product of the Philadelphia chromosome. BCR-ABL tyrosine kinase is present in virtually all patients with chronic myelogenous leukemia (CML) and some patients with acute lymphoblastic leukemia (ALL); it is considered the abnormality that causes CML.
- Imatinib inhibits tyrosine kinase activity of ABL in normal cells, although this is not considered clinically relevant. The compound has also shown high activity in blocking the tyrosine kinase activity of c-kit (stem-cell factor receptor) and platelet-derived growth factor receptor.
- Imatinib is indicated primarily for treatment of CML. However, activity might also be expected in tumors relying on expression of c-kit (eg, gastrointestinal stromal tumors), platelet-derived growth factor receptor, or ABL.
- Safety and efficacy have been demonstrated only in children ages 2 years of age and older with newly diagnosed Philadelphia chromosome-positive (Ph+), chronic phase chronic myeloid leukemia (CML) and in children 2 years of age and older with Ph+, chronic phase CML with recurrence after stem cell transplantation or resistance to interferon-alpha therapy

FORMULARY COVERAGE

Prior authorization: Required

Good Health Formulary: T4

Commercial Formulary: T4

Medicare Part D coverage: T4

COVERAGE CRITERIA

Gleevec (imatinib) meets the definition of **medical necessity** for the following:

FDA Labeled indications include:

- Acute lymphoid leukemia, Relapsed/Refractory Philadelphia chromosome-positive
- Chronic eosinophilic leukemia
- Chronic myeloid leukemia, Philadelphia chromosome-positive, accelerated phase or blast crisis
- Chronic phase chronic myeloid leukemia, Philadelphia chromosome-positive, after failure of interferon-alpha therapy
- Chronic phase chronic myeloid leukemia, Philadelphia chromosome-positive, newly diagnosed
- Chronic phase chronic myeloid leukemia, Philadelphia chromosome-positive, recurrence after stem cell transplant
- Dermatofibrosarcoma protuberans, Unresectable, recurrent and/or metastatic
- Gastrointestinal stromal tumor
- Hypereosinophilic syndrome

- Myelodysplastic syndrome, With PDGFR (platelet-derived growth factor receptor) gene rearrangement
- Myeloproliferative disorder, chronic, With PDGFR (platelet-derived growth factor receptor) gene rearrangement
- Systemic mast cell disease, Aggressive

Off-label uses which have shown favorable efficacy include:

- Acute lymphoid leukemia, Philadelphia chromosome-positive, newly diagnosed, as part of combination chemotherapy
- Chronic phase chronic myeloid leukemia, Philadelphia chromosome-positive, recurrence after stem cell transplant

Gleevec (imatinib) is considered **experimental** for the following:

- Liver carcinoma, Unresectable
- Metastatic melanoma, Monotherapy
- Myelofibrosis
- Ovarian cancer, Recurrent
- Polycythemia vera
- Rheumatoid arthritis

Required Provider Specialty:

- Approval is limited to Oncology

DOSAGE/ADMINISTRATION:

Adult Dosing

- Acute lymphoid leukemia, Philadelphia chromosome-positive, newly diagnosed, as part of combination chemotherapy: Optimal dosing and timing of imatinib mesylate is not yet defined in this setting; usual dose is 400 to 600 mg ORALLY daily
- Acute lymphoid leukemia, Relapsed/Refractory Philadelphia chromosome-positive: 600 mg ORALLY once daily until disease progression or unacceptable toxicity
- Chronic eosinophilic leukemia: 400 mg ORALLY once daily until disease progression or unacceptable toxicity
- Chronic eosinophilic leukemia: FIP1L1-PDGFR-alpha fusion kinase-positive patients, initial, 100 mg ORALLY once daily with dose titration to 400 mg if tolerated and if needed; continue until disease progression or unacceptable toxicity
- Chronic eosinophilic leukemia: consider the prophylactic use of systemic corticosteroids (1 to 2 milligrams/kilogram) for 1 to 2 weeks concomitantly with imatinib if an echocardiogram or serum troponin level is abnormal
- Chronic myeloid leukemia, Philadelphia chromosome-positive, accelerated phase or blast crisis: 600 mg ORALLY once daily until disease progression or unacceptable toxicity; consider increasing dosage to 800 mg per day, given as 400 mg ORALLY twice daily
- Chronic phase chronic myeloid leukemia, Philadelphia chromosome-positive, after failure of interferon-alpha therapy: 400 mg ORALLY once daily until disease progression or unacceptable toxicity; consider increasing dose to 600 mg ORALLY once daily
- Chronic phase chronic myeloid leukemia, Philadelphia chromosome-positive, newly diagnosed: 400 mg ORALLY once daily until disease progression or unacceptable toxicity; consider increasing to 600 mg ORALLY once daily
- Dermatofibrosarcoma protuberans, Unresectable, recurrent and/or metastatic: 800 mg ORALLY once daily until disease progression or unacceptable toxicity

- Gastrointestinal stromal tumor: adjuvant, 400 mg/day ORALLY; administered for 1 year in a clinical trial
- Gastrointestinal stromal tumor: unresectable/metastatic, 400 mg/day ORALLY; may increase up to 400 mg ORALLY twice daily; continue until disease progression or unacceptable toxicity
- Hypereosinophilic syndrome: 400 mg ORALLY once daily until disease progression or unacceptable toxicity
- Hypereosinophilic syndrome: FIP1L1-PDGFR-alpha fusion kinase-positive patients, initial, 100 mg ORALLY once daily with dose titration to 400 mg if tolerated and if needed; continue until disease progression or unacceptable toxicity
- Hypereosinophilic syndrome: consider the prophylactic use of systemic corticosteroids (1 to 2 milligrams/kilogram) for 1 to 2 weeks concomitantly with imatinib if an echocardiogram or serum troponin level is abnormal
- Myelodysplastic syndrome, With PDGFR (platelet-derived growth factor receptor) gene rearrangement: 400 mg ORALLY once daily until disease progression or unacceptable toxicity
- Myelodysplastic syndrome, With PDGFR (platelet-derived growth factor receptor) gene rearrangement: consider the prophylactic use of systemic corticosteroids (1 to 2 milligrams/kilogram) for 1 to 2 weeks concomitantly with imatinib if an echocardiogram or serum troponin level is abnormal in patients with high eosinophil levels
- Myeloproliferative disorder, chronic, With PDGFR (platelet-derived growth factor receptor) gene rearrangement: 400 mg ORALLY once daily until disease progression or unacceptable toxicity
- Myeloproliferative disorder, chronic, With PDGFR (platelet-derived growth factor receptor) gene rearrangement: consider the prophylactic use of systemic corticosteroids (1 to 2 milligrams/kilogram) for 1 to 2 weeks concomitantly with imatinib if an echocardiogram or serum troponin level is abnormal in patients with high eosinophil levels
- Systemic mast cell disease, Aggressive: without D816V c-Kit mutation, 400 mg ORALLY once daily until disease progression or unacceptable toxicity
- Systemic mast cell disease, Aggressive: c-Kit mutational status unknown, 400 mg ORALLY once daily if unresponsive to other therapies; continue until disease progression or unacceptable toxicity
- Systemic mast cell disease, Aggressive: with eosinophilia, initial, 100 mg ORALLY once daily; with dose titration to 400 mg if tolerated and if needed; continue until disease progression or unacceptable toxicity
- Systemic mast cell disease, Aggressive: consider the prophylactic use of systemic corticosteroids (1 to 2 milligrams/kilogram) for 1 to 2 weeks concomitantly with imatinib if an echocardiogram or serum troponin level is abnormal in patients with high eosinophil levels

Pediatric dosing

- Chronic phase chronic myeloid leukemia, Philadelphia chromosome-positive, after failure of interferon-alpha therapy: 2 years of age and older, 260 mg/m² ORALLY once a day; dose may be split into twice a day; continue until disease progression or unacceptable toxicity
- Chronic phase chronic myeloid leukemia, Philadelphia chromosome-positive, newly diagnosed: 2 years of age and older, 340 mg/m² ORALLY once a day, not to exceed 600 mg; dose may be split into twice a day; continue until disease progression or unacceptable toxicity
- Chronic phase chronic myeloid leukemia, Philadelphia chromosome-positive, recurrence after stem cell transplant: 2 years of age and older, 260 mg/m² ORALLY once a day; dose may be split into twice a day; continue until disease progression or unacceptable toxicity

Dosing adjustments

- Consult package insert/ prescribing information

PRECAUTIONS:

- Consult package insert/ prescribing information

Billing/Coding information

- n/a

COST

- AWP (April 2010):
 - 100mg tabs (1): \$46.29
 - 400mg tabs (1): \$166.79

COMMITTEE APPROVAL:

GUIDELINE UPDATE INFORMATION:

April 2010	Policy created

REFERENCES:

- DRUGDEX®, accessed 04/02/2010
- Product Information: GLEEVEC(R) oral tablets, imatinib mesylate oral tablets. Novartis Pharma Stein AG, Stein, Switzerland, 2008.