

DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Imatinib Drug Quantity Management (DQM) Policy – Per Rx

- Gleevec® (imatinib tablets – Novartis, generic)

REVIEW DATE: 12/07/2022

OVERVIEW

Indication

Imatinib, a tyrosine kinase inhibitor (TKI), is indicated for the treatment of:¹

- **Acute lymphoblastic leukemia (ALL)**, Philadelphia chromosome positive (Ph+), in adults with relapsed or refractory disease.
- **ALL**, newly diagnosed and Ph+, in combination with chemotherapy in pediatric patients.
- **Aggressive systemic mastocytosis**, in adults, without the D816V c-Kit mutation or with unknown c-Kit mutational status.
- **Chronic myeloid leukemia (CML)**, newly diagnosed and Ph+, in adult and pediatric patients in chronic phase.
- **CML**, Ph+, in blast phase, accelerated phase, or in chronic phase after failure of interferon alfa therapy.
- **Dermatofibrosarcoma protuberans** in adults with unresectable, current, and/or metastatic disease.
- **Gastrointestinal stromal tumors (GIST)**, in patients with Kit (CD117) positive unresectable and/or metastatic malignant disease.
- **GIST**, Kit (CD117) positive, as adjuvant treatment of adults following resection.
- **Hypereosinophilic syndrome and/or chronic eosinophilic leukemia**, adults who have the *FIP1L1-PDGFR* alpha fusion kinase (mutation analysis or fluorescence in situ hybridization demonstration of CICH2 allele deletion) for patients with hypereosinophilic syndrome and/or chronic eosinophilic leukemia who are *FIP1L1-PDGFR* alpha fusion kinase negative or unknown.
- **Myelodysplastic/myeloproliferative diseases**, associated with *PDGFR* gene rearrangements in adults.

Dosing

The recommended dose range of imatinib is 400 to 800 mg per day for its FDA-approved indications.¹ Likewise, literature supports dosing up to 800 mg per day for off-label uses.²⁻⁸ Pediatric dosing is based on body surface area and should not exceed a maximum dose of 600 mg per day.¹ Doses of 400 mg or 600 mg should be administered once daily, whereas a dose of 800 mg should be administered as 400 mg twice a day. For daily dosing of 800 mg and above, the 400 mg tablet should be used to reduce iron exposure.

The imatinib dose should be reduced to manage adverse events, moderate or severe renal impairment, severe hepatic impairment, or drug interactions with cytochrome P450 (CYP)3A4 inhibitors.¹ CYP3A4 inducers may decrease imatinib plasma concentrations. Therefore, the concomitant use of strong CYP3A4 inducers with imatinib should be avoided. However, if imatinib must be administered with a strong CYP3A4 inducer, the dose of imatinib should be increased by at least 50% and clinical response monitored. Doses of up to 1,200 mg per day of imatinib have been studied in combination with CYP3A4 inducers.

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Availability

Imatinib (Gleevec, generic) is available in 100 mg and 400 mg tablets.¹ The 100 mg tablets are supplied in bottles of 90, while the 400 mg tablets are supplied in blister packs of 30.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of imatinib tablets (Gleevec, generic). If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted below.

Automation: None.

Drug Quantity Limit(s)

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity Per Rx
Gleevec® (imatinib tablets, generic)	100 mg tablets	180 tablets ^a	540 tablets
	400 mg tablets	60 tablets ^b	180 tablets

^a 180 tablets is a quantity sufficient for a 30-day supply at retail and a 90-day supply at home delivery at the maximum recommended dose of 600 mg per day; ^b 60 tablets is quantity sufficient for a 30-day supply at retail or a 90-day supply at home delivery at a dose of 800 mg per day.

CRITERIA

Imatinib (Gleevec, generic) 100 mg tablets

No overrides recommended.

Imatinib (Gleevec, generic) 400 mg tablets

1. If the patient is taking a strong cytochrome P450 (CYP)3A4 inducer, approve the requested quantity not to exceed 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

Note: Examples of CYP3A4 inducers include dexamethasone, rifampin, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampentine, and St. John's Wort.

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