

SPECIALTY QUANTITY LIMIT PROGRAM

GLEEVEC (imatinib mesylate)

I. PROGRAM DESCRIPTION

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for all FDA-approved indications fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.

II. COVERED QUANTITIES

Medication	Standard Limit	FDA-recommended dosing
Gleevec (imatinib mesylate) 100 mg tablet	90 tablets per 30 days	Ph+ CML <ul style="list-style-type: none"> • Adults with CP: 400 mg orally daily • Adults with AP or BC: 600 mg orally daily • Pediatrics with CP: 340 mg/m²/day (not to exceed 600 mg) Ph+ ALL <ul style="list-style-type: none"> • Adults: 600 mg orally daily • Pediatrics: 340 mg/m²/day (not to exceed 600 mg)
Gleevec (imatinib mesylate) 400 mg tablet	60 tablets per 30 days	MDS/MPD: 400 mg orally daily ASM: 100 mg or/to 400 mg orally daily HES/CEL: 100 mg or/to 400 mg orally daily DFSP: 400 mg orally twice a day Metastatic and/or unresectable GIST: 400 mg orally daily up to 400 mg twice daily Adjuvant treatment of GIST: 400 mg orally daily

The limits may apply to the generic equivalent medication.

* ALL: acute lymphoblastic leukemia; ASM: aggressive systemic mastocytosis; CML: chronic myeloid leukemia; CML-AP: advanced phase; CML-CP: chronic phase; CML-BC-blast crisis; DFSP: dermatofibrosarcoma protuberans; GIST: gastrointestinal stromal tumors; HES/CEL: hypereosinophilic syndrome/chronic eosinophilic leukemia; MDS/MPD: myelodysplastic/myeloproliferative diseases; Ph+: Philadelphia chromosome positive

III. REFERENCES

1. Gleevec [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2018.
2. imatinib [package insert]. Cranbury, NJ: Sun Pharmaceuticals Inc.; November 2018.