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| Reference number |
| 1753-H |

SPECIALTY QUANTITY LIMIT PROGRAM

GILOTRIF (afatinib)

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 |
|------------------------|----------------|---|
| Gilotrif 20 mg tablets | 30 per 30 days | <ul style="list-style-type: none"> • Initial dose: 40 mg once daily • Dose adjustment for severe renal impairment: 30 mg once daily • Dose adjustment for adverse reactions: resume treatment when the adverse reaction fully resolves, returns to baseline, or improves to Grade 1. Reinstigate at a reduced dose (10 mg per day less than the dose at which the adverse reaction occurred) • Dose adjustment for drug interactions: <ul style="list-style-type: none"> ○ P-gp inhibitors: reduce daily dose by 10 mg. Resume the previous dose after discontinuation of the P-gp inhibitor. ○ P-gp inducers: increase daily dose by 10 mg. Resume the previous dose after discontinuation of the P-gp inducer. |
| Gilotrif 30 mg tablets | 30 per 30 days | |
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III. REFERENCE

1. Gilotrif [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; January 2018.