AFATINIB

Generic	Brand	HICL	GCN	Exception/Other
AFATINIB DIMALEATE	GILOTRIF	40478		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
   - Disease progression after platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
   - The patient's tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet per day.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **AFATINIB (Gilotrif)** requires a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) or metastatic non-small cell lung cancer (NSCLC). The following criteria must also be met:
   For the diagnosis of metastatic squamous non-small cell lung cancer (NSCLC), approval requires:
   - Disease progression after platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin).

   For the diagnosis of metastatic non-small cell lung cancer, approval requires:
   - Patient's tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test.

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AFATINIB

RATIONALE
Promote appropriate utilization of **Afatinib** based on FDA approved indications.

FDA APPROVED INDICATIONS
Gilotrif is a kinase inhibitor indicated for:

- First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test.
  - Limitation of Use: The safety and efficacy of Gilotrif have not been established in patients whose tumors have resistant EGFR mutations.

- Treatment of patients with metastatic, squamous NSCLC progressing after platinum-based chemotherapy.

DOSAGE AND ADMINISTRATION
The recommended dose of Gilotrif is 40 mg orally once daily until disease progression or no longer tolerated by the patient. Take Gilotrif at least 1 hour before or 2 hours after a meal.

For patients who require therapy with a P-glycoprotein (P-gp) inhibitor, *reduce* Gilotrif daily dose by 10 mg if not tolerated. Resume the previous dose after discontinuation of the P-gp inhibitor as tolerated.

For patients who require chronic therapy with a P-gp inducer, *increase* Gilotrif daily dose by 10 mg as tolerated. Resume the previous dose 2 to 3 days after discontinuation of the P-gp inducer.

Reduce dose to 30mg daily in patients with severe renal impairment (eGFR 15 to 29 ml/min).

Withhold Gilotrif in patients with NCI CTCAE Grade 3 or higher, diarrhea of Grade 2 or higher persisting for 2 or more consecutive days while taking anti-diarrheal medication, cutaneous reactions of Grade 2 that are prolonged (lasting more than 7 days) or intolerable, or renal impairment of Grade 2 or higher . Resume treatment when the adverse reaction fully resolves, returns to baseline, or improves to Grade 1, and resume at a reduced dose of 10mg per day less than the dose at which the adverse reaction occurred.

Permanently discontinue for life-threatening bullous, blistering, or exfoliative skin lesions, confirmed interstitial lung disease, severe drug-induced hepatic impairment, persistent ulcerative keratitis, symptomatic left ventricular dysfunction, and severe or intolerable adverse reaction occurring at a dose of 20 mg per day.

HOW SUPPLIED
Tablets: 40 mg, 30 mg, and 20 mg

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AFATINIB

REFERENCES

- Gilotrif (afatinib) [prescribing information]. Boehringer Ingelheim Pharmaceuticals, Inc.; Ridgefield, CT. January 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/05/18

Created: 10/13
Client Approval: 01/18

P&T Approval: 01/18