Reference number(s)
1658-A

Specialty Guideline Management
Gilotrif

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Gilotrif	afatinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

EGFR Mutation-Positive, Metastatic Non-Small Cell Lung Cancer

Gilotrif is indicated for the 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.

Limitations of Use

Safety and efficacy of Gilotrif were not established in patients whose tumors have resistant EGFR mutations.

Previously Treated, Metastatic Squamous NSCLC

Gilotrif is indicated for the treatment of patients with metastatic squamous NSCLC progressing after platinum-based chemotherapy.

Compendial Use[2]

NSCLC, recurrent, advanced or metastatic EGFR-sensitizing mutation-positive as a single agent or as subsequent therapy in combination with cetuximab.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: For NSCLC, EGFR mutation testing results (where applicable).

Coverage Criteria

Non-Small Cell Lung Cancer (NSCLC)[1,2]

- Authorization of 12 months may be granted for treatment of recurrent, advanced or metastatic NSCLC when the member has EGFR-sensitizing mutation-positive disease as a single agent or in combination with cetuximab.
- Authorization of 12 months may be granted for treatment of metastatic squamous NSCLC progressing after platinum-based chemotherapy.

Continuation of Therapy

NSCLC

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for NSCLC when either of the following criteria are met:

- There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
- Disease is T790M negative and there is no evidence of unacceptable toxicity.

References

1. Gilotrif [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; April 2022.

2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 3, 2025.