CVS Caremark®

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| 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 Indications1

#### 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 Use2

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.