PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Gilotrif Prior Authorization Policy
- Gilotrif® (afatinib tablets – Boehringer Ingelheim)

REVIEW DATE: 12/11/2024

OVERVIEW

Gilotrif, a tyrosine kinase inhibitor (TKI), is indicated for the following uses:[1]

- **Non-small cell lung cancer (NSCLC)**, first-line treatment of patients with metastatic disease whose tumors have non-resistant epidermal growth factor receptor (*EGFR*) mutations as detected by an FDA-approved test.
  Limitations of use: The safety and efficacy of Gilotrif have not been established in patients whose tumors have resistant *EGFR* mutations.
- **NSCLC, squamous cell,** for the treatment of patients with metastatic disease progressing after platinum-based chemotherapy.

Guidelines

Gilotrif has been addressed in National Comprehensive Cancer Network (NCCN) guidelines.[2-4]

- **Head and Neck Cancer:** Guidelines (version 1.2025 – November 26, 2024) recommend Gilotrif as a single agent for the treatment of recurrent, unresectable, or metastatic non-nasopharyngeal cancers (lip, oral cavity, oropharynx, hypopharynx, glottis, larynx, supraglottic, larynx, ethmoid sinus, maxillary sinus, occult primary) in patients with disease progression or after platinum-based therapy (category 2B).[3]
- **Non-Small Cell Lung Cancer (NSCLC)**: Guidelines (version 11.2024 – October 15, 2024) recommend testing for sensitizing *EGFR* mutations in patients with metastatic disease.[4] Patients with sensitizing *EGFR* mutations have a significantly better response to the *EGFR* TKIs (erlotinib, Gilotrif, Iressa®, Tagrisso®, and Vizimpro). The most common *EGFR* mutations are exon 19 deletions and exon 21 (L858R) substitution mutations. Other less common mutations that are also sensitive to *EGFR* TKIs include L861Q, G719X, and S768I; these mutations cumulatively account for approximately 10% of all *EGFR* mutations. NCCN recommends the *EGFR* TKIs as first-line treatment for patients with advanced or metastatic NSCLC with *EGFR* exon 19 deletions, exon 21 (L858R) substitution mutations, S768I, L861Q, G719X, and S768I. Gilotrif is a category 1 recommendation under "Useful in Certain Circumstances" for *EGFR* exon 19 deletions and exon 21 substitutions. It is a "Preferred" first-line therapy (category 2A) for *EGFR* S768I, L861Q, and/or G719X mutations. NCCN does not recommend Gilotrif monotherapy for use as second-line treatment for patients with squamous cell NSCLC (without *EGFR* mutations); Gilotrif + Erbitux® (cetuximab injection) may be considered in patients with disease progression on *EGFR* TKI therapy. Gilotrif is not recommended in the guidelines for squamous cell NSCLC. However, it remains FDA-approved for this indication.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Gilotrif. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Gilotrif is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Non-Small Cell Lung Cancer – Epidermal Growth Factor Receptor (*EGFR*) Mutation-Positive.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has advanced or metastatic disease; AND
   C) Patient has sensitizing *EGFR* mutation-positive non-small cell lung cancer as detected by an approved test.
   Note: Examples of sensitizing *EGFR* mutation-positive non-small cell lung cancer include the following: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X, and S768I.

2. **Non-Small Cell Lung Cancer – Squamous Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has metastatic squamous cell carcinoma; AND
   C) Patient has disease progression after treatment with platinum-based chemotherapy.

Other Uses with Supportive Evidence

3. **Head and Neck Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has non-nasopharyngeal head and neck cancer; AND
   Note: Examples of non-nasopharyngeal head and neck cancer are lip, oral cavity, oropharynx, hypopharynx, glottis, larynx, supraglottic larynx, ethmoid sinus, maxillary sinus, and occult primary.
   C) Patient has disease progression on or after platinum-based chemotherapy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Gilotrif is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Gilotrif™ tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; April 2022.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 6, 2024. Search terms: afatinib.
3. The NCCN Head and Neck Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – November 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 6, 2024.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 11.2024 – October 15, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 6, 2024.