PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 12/16/2020

OVERVIEW

Gilotrif is a tyrosine kinase inhibitor (TKI) indicated for the following:

- **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 a FDA-approved test.[1] The safety and efficacy of Gilotrif have not been established in patients whose tumors have resistant *EGFR* mutations.
- **NSCLC, squamous,** for the treatment of patients with metastatic disease progressing after platinum-based chemotherapy.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for NSCLC (version 1.2021 – November 25, 2020) recommend Tarceva® (erlotinib tablets), Iressa® (gefitinib tablets), Gilotrif, Vizimpro® (dacomitinib tablets), and Tagrisso™ (osimertinib tablets) as Category 1 recommended options for the first-line treatment in patients with sensitizing *EGFR*-mutation positive NSCLC.[3] Tagrisso is noted as an "preferred" option in the first-line setting. Upon disease progression, T790M testing is recommended in guidelines. NCCN added a footnote to this recommendation to also consider Gilotrif and Erbitux® (cetuximab for injection) combination regimen in patients with disease progression (T790M-negative multiple systemic lesions) on EGFR-TKI therapy (category 2A). This is based on data demonstrating similar response rates with this combination therapy in patients with T790M mutation-positive or mutation-negative tumors in pre-treated patients with NSCLC. NCCN notes that for squamous cell carcinoma, Gilotrif is not used in the second-line setting at NCCN institutions for these indications related to the efficacy and safety of these agents compared to the efficacy and safety of other available agents.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Gilotrif. All approvals are provided for 3 years in duration as noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Non-Small Cell Lung Cancer (NSCLC) – Epidermal Growth Factor Receptor (EGFR) Mutation-Positive.** Approve for 3 years if the patient meets the following criteria (A and B):
   A) Patient has *metastatic* NSCLC; AND
   B) Patient has non-resistant *EGFR* mutation-positive NSCLC as detected by an approved test.

2. **Non-Small Cell Lung Cancer (NSCLC) – Squamous Cell Carcinoma.** Approve for 3 years if the patient meets the following criteria (A and B):
   A) Patient has metastatic squamous cell carcinoma; AND
   B) Patient has disease progression after treatment with 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; October 2019.
2. The NCCN Drugs & Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 14, 2020. Search terms: afatinib.
3. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2021 – November 25, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 14, 2020.