UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Gilotrif

Program	Prior Authorization
Medication	Gilotrif® (afatinib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	12/2015
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Gilotrif® (afatinib) is kinase inhibitor 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. Gilotrif is also indicated for the treatment of patients with metastatic squamous NSCLC progressing after platinum-based chemotherapy.[1] The National Cancer Comprehensive Network (NCCN) also recommends the use of Gilotrif in patients with advanced non-nasopharyngeal head and neck cancers with progression on or after platinum-containing chemotherapy.[2]

2. Coverage Criteria:

A. <u>Non-Small Cell Lung Cancer (NSCLC)</u>

1. <u>Initial Authorization</u>

a. **Gilotrif** will be approved based on **<u>both</u>** of the following criteria:

(1) Diagnosis of metastatic non-small cell lung cancer (NSCLC)

-AND-

(2) **<u>One</u>** of the following:

(a) Squamous disease progressing after previous platinum-based chemotherapy
(b) Tumors are positive for non-resistant epidermal growth factor receptor (EGFR) mutations

Authorization will be issued for 12 months.

2. Reauthorization

a. **Gilotrif** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Gilotrif therapy.

Authorization will be issued for 12 months.

B. Non- Nasopharyngeal Head and Neck Cancer

1. Initial Authorization

a. Gilotrif will be approved based on **both** of the following criteria:

(1) Diagnosis of advanced, non-nasopharyngeal head and neck cancer

-AND-

(2) Disease has progressed on or after platinum-containing chemotherapy

Authorization will be issued for 12 months.

2. Reauthorization

a. Gilotrif will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Gilotrif therapy.

Authorization will be issued for 12 months.

C. Extensive Brain Metastases

1. Initial Authorization

a. Gilotrif will be approved based on the following criteria:

(1) Diagnosis of brain metastasis due to EGFR-sensitizing mutation positive non-small cell lung cancer

-AND-

(2) Disease is **one** of the following:
   a. Recurrent
   b. Relapsed

-AND-

Authorization will be issued for 12 months.

2. Reauthorization

a. Gilotrif will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Gilotrif therapy.

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

1. Initial Authorization

a. **Gilotrif** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Gilotrif** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Gilotrif therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Gilotrif [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc., October 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 29, 2020.

Program	Prior Authorization - Gilotrif (afatinib)
Change Control	
Date	Change
12/2015	New guideline –combined Gilotrif, Iresssa, and Tarceva into a single policy due to similar criteria
6/2016	Updated clinical criteria to align with Employer & Individual notification policy, separated Gilotrif, Iressa, and Tarceva into separate policies to align with Employer & Individual policies, and updated policy template
6/2017	Added additional coverage for advanced non-nasopharyngeal head and neck cancer based on NCCN guidelines. Updated background and references.
6/2018	Updated background and criteria to align with updated labeled indication. Added NCCN recommended review criteria. Updated references.
6/2019	Annual review with no change to coverage criteria. Updated background and reference.
6/2020	Annual review. Added brain metastases coverage based on NCCN guidelines. Updated background and references. Added Additional Clinical Rules section.