UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Gilotrif

Program	Prior Authorization
Medication	Gilotrif® (afatinib)
Issue Date	12/2015
Pharmacy and Therapeutics Approval Date	6/2017
Effective Date	8/2017

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 epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution 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 NSCLC that have activity against HER2 mutations or a known sensitizing EGFR mutation, and in patients with advanced non-nasopharyngeal head and neck cancers with progression on or after platinum-containing chemotherapy.[2]

2. Coverage Criteria:

A. Non-Small Cell Lung Cancer (NSCLC)

1. Initial Authorization

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

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

-AND-

(2) **One** of the following:

(a) Squamous disease progressing after previous platinum-based chemotherapy
(b) Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions
(c) Tumors are positive for exon 21 (L858R) substitution mutations
(d) Tumors are positive for HER2 mutation [off-label]

(e) Tumors are positive for a known sensitizing EGFR mutation (e.g,. in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation) [off-label]

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 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) Documentation of positive clinical response to therapy.

Authorization will be issued for 12 months.

3. References:

1. Gilotrif [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc., October 2016.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 6, 2016.

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.