UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1036-15
Program	Prior Authorization/Notification
Medication	Gilotrif® (afatinib)
P&T Approval Date	10/2013, 2/2014, 2/2015, 2/2016, 6/2016, 6/2017, 6/2018, 6/2019, 6/2020, 6/2021, 6/2022, 6/2023, 6/2024, 6/2025, 6/2026
Effective Date	9/1/2026

1. Background:

Gilotrif® (afatinib) is a 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. Additionally, the NCCN also recommends use of Gilotrif as a single-agent treatment for brain metastases in patients with EGFR sensitizing mutation positive NSCLC.[2]

Limitations of Use: Safety and efficacy of Gilotrif were not established in patients whose tumors have resistant EGFR mutations.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

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

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

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

1. **<u>Initial Authorization</u>**

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

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

-AND-

(2) Disease is recurrent, advanced, or metastatic

-AND-

(3) **One** 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.

C. Non- Nasopharyngeal Head and Neck Cancer

1. **Initial Authorization**

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

(1) Diagnosis of 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.

D. Brain Metastases

1. **Initial Authorization**

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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

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.

E. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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.; April 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed April 28, 2026.

Program	Prior Authorization/Notification - Gilotrif (afatinib)
Change Control	
10/2013	New program for Gilotrif approved by FDA on 7/12/2013.
2/2014	Review with no change to Coverage Criteria.
2/2015	Annual review. Added coverage for HER2-positive NSCLC. Updated background and references.

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2/2016	Annual review. Changed initial and reauthorization period to 12 months. Updated references.
6/2016	Added additional coverage based on new FDA indication and NCCN guidelines. Updated background and references.
6/2017	Added additional coverage for advanced non-nasopharyngeal head and neck cancer based on updated NCCN guidelines. Updated background and references.
6/2018	Annual review. Updated background and criteria to align with updated labeled indication. 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.
6/2021	Annual review. Updated brain metastases coverage based on NCCN guidelines. Updated background and references.
6/2022	Annual review with no changes to criteria. Updated background with limitations of use and updated references.
6/2023	Annual review. Updated background. Added state mandate footnote. Updated references.
6/2024	Annual review. No changes to clinical criteria.
6/2025	Annual review. No changes to coverage criteria.
6/2026	Annual review. Updated coverage criteria for non-small cell lung cancer and non-nasopharyngeal head and neck cancer to align with NCCN. Updated references.

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