Clinical Policy: Afatinib (Gilotrif)

Reference Number: PA.CP.PHAR.298
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness clinical policy for afatinib (Gilotrif®) tablets for oral use.

FDA Approved Indication(s)
Gilotrif is indicated for:

- 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.
- Treatment of patients with metastatic squamous NSCLC progressing after platinum-based chemotherapy.

Limitation(s) of Use: The safety and efficacy of Gilotrif have not been established in patients whose tumors have resistant EGFR mutations.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Gilotrif is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all):

1. Diagnosis of non-small cell lung cancer (NSCLC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is recurrent or metastatic;
5. Member meets one of the following (a or b):
   a) Disease is positive for any of the following sensitizing EGFR mutations: exon 19 deletion, exon 21 [L858R] substitution, L861Q, G719X, or S768I mutations, as detected by an FDA-approved test;
   b) Disease is squamous and has progressed after platinum-based chemotherapy (e.g., cisplatin, carboplatin);
6. Dose does not exceed 40 mg per day (1 tablet per day).

Approval duration: 6 months

B. NCCN-Recommended Off-Label Uses (off-label) (must meet all):

1. Diagnosis of central nervous system cancer with brain metastases, as supported by NCCN categories 2A;
2. Prescribed by or in consultation with an oncologist;
3. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Other diagnoses/indications: Refer to PA. CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. All Covered Indications (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 40 mg per day (1 tablet per day).

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Gilotrif tablets contain afatinib, a tyrosine kinase inhibitor which is a 4-anilinoquinazoline. Afatinib covalently binds to the kinase domains of EGFR (ErbB1), HER2 (ErbB2), and HER4 (ErbB4) and irreversibly inhibits tyrosine kinase autophosphorylation, resulting in downregulation of ErbB signaling. Afatinib demonstrated inhibition of autophosphorylation and in vitro proliferation of cell lines expressing wildtype EGFR or those expressing selected EGFR exon 19 deletion mutations or exon 21 L858R mutations, including some with a secondary T790M mutation, at afatinib concentrations achieved, at least transiently, in patients. In addition, afatinib inhibited in vitro proliferation of cell lines overexpressing HER2. Treatment with afatinib resulted in inhibition of tumor growth in nude mice implanted with tumors either overexpressing wild type EGFR or HER2 or in an EGFR L858R/T790M double mutant model.

Formulations:

Gilotrif tablets for oral administration are available in 40 mg, 30 mg, or 20 mg of afatinib (equivalent to 59.12 mg, 44.34 mg, or 29.56 mg afatinib dimaleate, respectively).

Appendices

Appendix A: Abbreviation Key

EGFR: epidermal growth factor receptor
HER2: human epidermal growth factor receptor 2
NSCLC: non-small cell lung cancer

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
New indication: updated FDA approved indication and approval criteria to allow coverage for the following uncommon EGFR mutations: L861Q, G719X, and S768I for metastatic NSCLC with sensitizing EGFR mutation; added NCCN 2A recommended off-label use for central nervous system cancer with brain metastases; references reviewed and updated.	02.13.18	

References

1. Gilotrif Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; January 2018Available at: http://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Gilotrif/Gilotrif.pdf?DMW_FORMAT=pdf. Accessed March 2, 2018.
2. Afatinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed March 2, 2018.
3. Non-small cell lung cancer (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed March 2, 2018.