Clinical Policy: Afatinib (Gilotrif)

Reference Number: PA.CP.PHAR.298
Effective Date: 01/18
Last Review Date: 04/19

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 recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;

4. Member meets one of the following (a or b):
   a. Disease is positive for a sensitizing EGFR mutation (e.g., exon 19 deletion or insertion; exon 21 point mutation - L858R, L861Q; exon 18 point mutation - G719X; exon 20 point mutation - S768I);
   b. Squamous cell carcinoma histology with progression after platinum-based chemotherapy (e.g., cisplatin, carboplatin);
5. Request meets one of the following (a or b):
   a. Dose does not exceed 40 mg (1 tablet) per day;
   b. 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.PMN.53.

II. Continued Approval

A. Non-Small Cell Lung Cancer (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, request meets one of the following (a or b):
    a. New dose does not exceed 40 mg (1 tablet) per day;
    b. New 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

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.PMN.53.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
NSCLC: non-small cell lung cancer

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Platinum-based chemotherapy (e.g., cisplatin, carboplatin)	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

None reported

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	40 mg PO QD	40 mg/day

V. Product Availability

Tablets: 20 mg, 30 mg, 40 mg

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	
2Q 2019 annual review: NCCN designation of advanced added to NSCLC; EGFR mutations restated as examples; NSCLC CNS metastasis moved from off-label section and incorporated into NSCLC criteria set; references reviewed and updated.	04.17.19	

References

1. Gilotrif Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; January 2018. Available at: http://gilotrif.com. Accessed January 24, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed January 24, 2019.
3. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer (Version 3.2019). Available at www.nccn.org. Accessed January 24, 2019.
4. National Comprehensive Cancer Network Guidelines. Central Nervous System Cancers Version 2.2018. Available at www.nccn.org. Accessed January 24, 2019.