Clinical Policy Title:	afatinib
Policy Number:	RxA.151
Drug(s) Applied:	Gilotrif®
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of recurrent, advanced or metastatic NSCLC;
2. The requested medication and member diagnosis meet one of the following (a, b or c):
   a. Used as a single agent for disease that is positive for a sensitizing EGFR mutation (e.g., exon 19 deletion or L858R);
   b. Used as a single agent for squamous cell carcinoma histology with progression after platinum-based chemotherapy (e.g., cisplatin, carboplatin);
   c. Used as a subsequent therapy in combination with cetuximab for EGFR exon 19 deletion or L858R or EGFR S7681, L861Q and/or G719X mutation positive recurrent, advanced, or metastatic disease, and one of the following (i, ii or iii);
      i. Patient progressed on EGFR tyrosine kinase inhibitor therapy and has asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited metastases;
      ii. Patient has T790M mutation-negative disease that progressed on EGFR tyrosine kinase inhibitor therapy and has multiple symptomatic systemic lesions;
      iii. Patient has T790M mutation-positive disease that progressed on osimertinib and has multiple symptomatic systemic lesions.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

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

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer. Version 6.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Continued Therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 2. I.A.4.a was updated to remove, “insertion; exon 21 point mutation L8618……S7681.” 3. References were reviewed and updated.	02/19/2021	09/14/2021
Policy was reviewed: 1. Initial Approval Criteria, I.4.A.a: Updated disease progression criteria from disease is positive for a sensitizing EGFR mutation (e.g., exon 19 deletion or L858R)to use as a single agent for disease that is positive for a sensitizing EGFR mutation (e.g., exon 19 deletion or L858R). 2. Initial Approval Criteria, I.4.A.b: Updated disease progression criteria from squamous cell carcinoma histology with progression after platinum-based chemotherapy (e.g., cisplatin, carboplatin) to use as a single agent for squamous cell carcinoma histology with progression after platinum-based chemotherapy (e.g., cisplatin, carboplatin) 3. Initial Approval Criteria, 1.A.4.c: Updated to include new combination therapy criteria Used as a subsequent therapy in combination with cetuximab for EGFR exon 19 deletion or L858R or EGFR S7681, L861Q and/or G719X mutation positive recurrent, advanced, or metastatic disease; (i, ii or iii); i. Patient progressed on EGFR tyrosine kinase inhibitor therapy and has asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited metastases; ii. Patient has T790M mutation-negative disease that progressed on EGFR tyrosine kinase inhibitor therapy and has multiple symptomatic systemic lesions; iii. Patient has T790M mutation-positive disease that progressed on osimertinib and has multiple symptomatic systemic lesions. 4. Initial Approval Criteria, I.A.5: Updated dosing	02/02/2022	04/18/2022

criteria from 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). to Request meets one of the following (a or b): a. Dose does not exceed 40 mg per day; b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence). *Prescribed regimen must be FDA-approved or recommended by NCCN 5. Continued Therapy Approval Criteria, II.A.3: Updated dosing criteria from 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). to If request is for a dose increase, request meets one of the following (a or b): a. New dose does not exceed 40 mg 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). *Prescribed regimen must be FDA-approved or recommended by NCCN 6. References were reviewed and updated.		
Policy was reviewed: 1. References were reviewed and updated.	01/18/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed prescriber restrictions. 2. Removed age restrictions. 3. Removed dose restrictions.	08/28/2024	9/13/2024

4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.		