

<b>Clinical Policy Title:</b>	afatinib
<b>Policy Number:</b>	RxA.151
<b>Drug(s) Applied:</b>	Gilotrif®
<b>Original Policy Date:</b>	02/07/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	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](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
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This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Policy established.	01/2020	02/07/2020
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>Continued Therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance...”.</li> <li>I.A.4.a was updated to remove, “insertion; exon 21 point mutation L8618.....S7681.”</li> <li>References were reviewed and updated.</li> </ol>	02/19/2021	09/14/2021
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>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).</li> <li>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)</li> <li>Initial Approval Criteria, I.4.A.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); <ol style="list-style-type: none"> <li>Patient progressed on EGFR tyrosine kinase inhibitor therapy and has asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited metastases;</li> <li>Patient has T790M mutation-negative disease that progressed on EGFR tyrosine kinase inhibitor therapy and has multiple symptomatic systemic lesions;</li> <li>Patient has T790M mutation-positive disease that progressed on osimertinib and has multiple symptomatic systemic lesions.</li> </ol> </li> <li>Initial Approval Criteria, I.4.A.5: Updated dosing criteria from Request meets one of the following (a or b): <ol style="list-style-type: none"> <li>Dose does not exceed 40 mg (1 tablet)</li> </ol> </li> </ol>	02/02/2022	04/18/2022

<p>per day;</p> <p>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):</p> <p>a. Dose does not exceed 40 mg per day;</p> <p>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</p> <p>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):</p> <p>a. New dose does not exceed 40 mg (1 tablet) per day;</p> <p>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):</p> <p>a. New dose does not exceed 40 mg per day;</p> <p>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</p> <p>6. References were reviewed and updated.</p>		
<p>Policy was reviewed: 1. References were reviewed and updated.</p>	<p>01/18/2023</p>	<p>04/13/2023</p>
<p>Policy was reviewed.</p>	<p>10/19/2023</p>	<p>10/19/2023</p>
<p>Policy was reviewed: 1. Removed prescriber restrictions. 2. Removed age restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.</p>	<p>08/28/2024</p>	<p>9/13/2024</p>

5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.		
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025