RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	afatinib
Policy Number:	RxA.151
Drug(s) Applied:	Gilotrif®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Afatinib (Gilotrif®) is a kinase inhibitor. It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Afatinib (Gilotrif®)	NSCLC	40 mg PO once daily	40 mg/day

Dosage Forms

- Tablets: 20 mg, 30 mg, 40 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

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

1. Diagnosis of recurrent, advanced or metastatic 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
Commercial: 12 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving Gilotrif for a covered indication and has received this medication for at least 30 days;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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

- Contraindication(s):
  - None reported

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information
Not applicable

References

1. Gilotrif Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2019. Available at: https://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Gilotrif/Gilotrif.pdf?DMW_FORMAT=pdf. Accessed July 6, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed July 6, 2020.
3. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer (Version 6.2020). Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf. Accessed July 6, 2020.
4. National Comprehensive Cancer Network Guidelines. Central Nervous System Cancers Version 2.2020 Available at https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed July 6, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated. 2. Line of Business Policy Applies to was updated to all lines of business. 3. Continued therapy criteria II.A.1 rephrased to "Currently receiving medication that has been authorized by RxAdvance.." 4. Initial and Continued Therapy Approval criteria: Commercial approval duration was updated from length of benefit to 12 months. 5. References were updated.	07/06/2020	09/14/2020