Gilotrif™ (afatinib)
(Oral)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC unit]:

- 20 mg tablets: 1 tablet per day
- 30 mg tablets: 1 tablet per day
- 40 mg tablets: 1 tablet per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 40 mg per day

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**

Non-Small Cell Lung Cancer (NSCLC) †/Φ [1-6]

- Patient has metastatic disease with squamous-cell histology that progressed after platinum-based therapy; **AND**
  - Used as a single agent; **OR**
- Patient has non-resistant epidermal growth factor receptor (EGFR) mutation(s) as detected by any FDA or CLIA-compliant test ❖; **AND**
  - Used for recurrent, advanced or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
    - Used as a single agent; **AND**
      - Used as first-line therapy; **OR**

- Used as continuation of therapy following progression on afatinib for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions; **OR**

- Used as subsequent therapy in combination with cetuximab, in patients who have progressed on EGFR tyrosine kinase inhibitor therapy; **AND**
  - Patient has asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions; **OR**
  - Patient is T790M mutation negative and has multiple symptomatic systemic lesions

❖*If confirmed using an FDA approved assay - http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s) ; Φ Orphan Drug

IV. Renewal Criteria [1,3]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe or prolonged diarrhea, severe cutaneous reactions, interstitial lung disease, hepatotoxicity, gastrointestinal perforation, ulcerative keratitis, etc.; **AND**
  - Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **OR**
  - For continuation therapy following afatinib progression, disease response is defined as lack of continued disease progression, improvement in tumor size, or improvement in patient symptoms

V. Dosage/Administration [1]

Indication	Dose
Non-Small Cell Lung Cancer	Administer 40 mg, orally, once daily until disease progression or no longer tolerated by the patient.

VI. Billing Code/Availability Information

HCPCS code:

- J8999 – Prescription drug, oral, chemotherapeutic, nos

NDC:

- 20 mg tablet – 00597-0141-xx

- 30 mg tablet – 00597-0137-xx
- 40 mg tablet – 00597-0138-xx

VII. References

1. Gilotrif [package insert]. Ridgefield, CT; Boehringer Ingelheim Pharmaceuticals, Inc; January 2018. Accessed March 2020.
2. Sequist LV, Yang JC, Yamamoto N, et al. Phase III Study of Afatinib or Cisplatin Plus Pemetrexed in Patients With Metastatic Lung Adenocarcinoma With EGFR Mutations. J Clin Oncol, 31 (27), 3327-34; 2013 Sep 20. PMID: 23816960. DOI: 10.1200/JCO.2012.44.2806
3. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) afatinib. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2020.
4. Yang JC, Shih J, Su W, et al. Afatinib for Patients With Lung Adenocarcinoma and Epidermal Growth Factor Receptor Mutations (LUX-Lung 2): A Phase 2 Trial. Lancet Oncol, 13 (5), 539-48; May 2012. PMID: 22452895. DOI: 10.1016/S1470-2045(12)70086-4
5. Wu Y, Zhou C, Hu C, et al. Afatinib Versus Cisplatin Plus Gemcitabine for First-Line Treatment of Asian Patients With Advanced Non-Small-Cell Lung Cancer Harbouring EGFR Mutations (LUX-Lung 6): An Open-Label, Randomised Phase 3 Trial. Lancet Oncol, 15 (2), 213-22; Feb 2014. PMID: 24439929. DOI: 10.1016/S1470-2045(13)70604-1
6. Soria J, Felip E, Cobo M, et al. Afatinib Versus Erlotinib as Second-Line Treatment of Patients With Advanced Squamous Cell Carcinoma of the Lung (LUX-Lung 8): An Open-Label Randomised Controlled Phase 3 Trial. Lancet Oncol, 16 (8), 897-907; Aug 2015. PMID: 26156651. DOI: 10.1016/S1470-2045(15)00006-6

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung

C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC