Iressa® (gefitinib)
(Oral)

Document Number: IC-0252

Last Review Date: 07/03/2018
Date of Origin: 07/28/2015
Dates Reviewed: 07/2015, 07/2016, 08/2017, 07/2018

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 250 mg tablets: 1 tablet per day

B. Max Units (per dose and over time) [Medical Benefit]:

- 1 billable unit daily

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Used as a single agent therapy: **AND**
- Patient is at least 18 years old; **AND**
- Patient's tumor has EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as confirmed by a FDA-approved test; **AND**

Non-small cell lung cancer †

- Patient's disease is metastatic or recurrent (excluding locoregional recurrence with no evidence of disseminated disease); **AND**
    - Used as first-line therapy; **OR**
    - Used as continuation therapy in patients with disease progression while on gefitinib for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions ‡

Central Nervous System Cancers ‡

- Patient has brain metastases from EGFR mutation-positive non-small cell lung cancer; **AND**
- Patient has recurrent brain metastases; **AND**

- Patient has stable systemic disease or has other reasonable systemic treatment options (*i.e. reasonable options include a trial of systemic therapy with a cytotoxic, targeted or immune modulating agent that has good CNS penetration)*

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in Section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: interstitial lung disease, hepatotoxicity, gastrointestinal perforation, severe/persistent diarrhea, ocular disorders including keratitis, and bullous and exfoliative skin disorders, etc.

V. Dosage/Administration

Indication	Dose
Non-small cell lung cancer	250 mg orally once daily* *Patients receiving treatment with a strong CYP3A4 inducer (e.g. rifampicin, phenytoin, or tricyclic antidepressants) require dose escalation to 500 mg daily

VI. Billing Code/Availability Information

HCPCS code:

- J8565 - Gefitinib, oral, 250 mg: 1 billable unit = 250 mg

NDC:

- 250 mg tablet: 00310-0482-xx

VII. References

1. Iressa [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; July 2015. Accessed June 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for gefitinib. National Comprehensive Cancer Network, 2018. 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 June 2018.

Appendix 1 – Covered Diagnosis Codes

ICD-10 Codes	Diagnosis
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
C79.31	Secondary malignant neoplasm of brain
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) and Local Coverage Determinations (LCDs) 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): 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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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 Government Benefit Administrators, 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