Iressa® (gefitinib)
(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]:

- Iressa 250 mg tablets: 1 tablet per day

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

- 1 billable unit daily

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1,2]

- Used as single agent therapy; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with gastric acid-reducing agents (e.g., proton pump inhibitors, histamine H2-receptor antagonists, and antacids), or if acid-reduction therapy is required, it will be administered at staggered administration times; **AND**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

Non-Small Cell Lung Cancer † Φ [1-3]

- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Patient has one of the following molecular mutations as confirmed by an FDA-approved or CLIA-compliant test❖: EGFR exon 19 deletion, EGFR exon 21 L858R substitution, or EGFR S768I, L861Q, and/or G719X mutation positive tumors; **AND**
  - Used as first-line therapy; **OR**
  - Used as continuation of therapy following disease progression on gefitinib for asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited* metastases ‡; **AND**
    - Used for T790M mutation-negative disease

***** *Limited number is undefined but clinical trials have included 3 to 5 metastases.*

❖ *If confirmed using an immunotherapy assay* -http://www.fda.gov/CompanionDiagnostics

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

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other 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: interstitial lung disease, hepatotoxicity, gastrointestinal perforation, severe/persistent diarrhea, ocular disorders including keratitis, bullous and exfoliative skin disorders, 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 gefitinib 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	Recommended dose is 250 mg orally once daily, without regard to food until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

- Iressa 250 mg oral tablet: 00310-0482-xx

VII. References

1. Iressa [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; May 2021. Accessed June 2022
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for gefitinib. National Comprehensive Cancer Network, 2022. 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 2022.
3. Fukuoka M, Wu Y, Thongprasert S, et al. Biomarker Analyses and Final Overall Survival Results From a Phase III, Randomized, Open-Label, First-Line Study of Gefitinib Versus Carboplatin/Paclitaxel in Clinically Selected Patients With Advanced Non–Small-Cell Lung Cancer in Asia (IPASS). J Clin Oncol 29:2866-2874.

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
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 Article (LCA) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/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)
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