Clinical Policy: Gefitinib (Iressa)

Reference Number: CP.PHAR.68
Effective Date: 11.16.16
Last Review Date: 05.18
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Gefitinib (Iressa®) is a kinase inhibitor.

FDA Approved Indication(s)
Iressa is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

Limitation(s) of use: Safety and efficacy of Iressa have not been established in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

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

It is the policy of health plans affiliated with Centene Corporation® that Iressa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is recurrent or metastatic;
5. Disease is positive for an EGFR mutation (exon 19 deletions or exon 21 [L858R] substitution) as detected by an FDA-approved test;
6. Request meets one of the following (a or b):
   a. Dose does not exceed 250 mg (1 tablet) per day (500 mg [2 tablets] per day if receiving a strong CYP3A4 inducer);
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Medicaid - 6 months
Commercial - Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Iressa for NSCLC 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 250 mg (1 tablet) per day (500 mg [2 tablets] per day if receiving a strong CYP3A4 inducer);
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Medicaid - 12 months
Commercial - Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

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

Not applicable

Appendix C: General Information

- Advanced disease is defined as recurrence or metastatic (spread of cancer to other sites).
- According to National Comprehensive Cancer Network (NCCN) Practice Guidelines, treatment of NSCLC (with category 1 NCCN recommendation) is further categorized by

histological findings with gene alteration and rearrangement: 1) EGFR mutation and ALK negative - platinum-based chemotherapy (e.g. cisplatin+Alimta®), 2) EGFR mutation positive - Gilotrif™, Tarceva®, Iressa®, and 3) ALK positive – Xalkori®, Alecensa®, Zykadia®.

- Iressa is currently being studied for locally advanced or recurrent squamous cell skin cancer, acute myelogenous leukemia, glioblastoma multiforme, refractory solid tumors, advanced head & neck cancer, advanced unresectable hepatocellular carcinoma (liver cancer), advanced renal cell carcinoma, metastatic breast cancer, and metastatic or locally recurrent colorectal cancer.
- Iressa has an NCCN 2A recommendation for use as a single agent for brain metastases if active against the primary tumor (EGFR-positive NSCLC).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	250 mg PO QD	250 mg/day (500 mg/day if receiving a strong CYP3A4 inducer)

VI. Product Availability

Tablet: 250 mg

VII. References

1. Iressa Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP. July 2015. Available at www.iressa.com. Accessed January 4, 2018.
2. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer. Version 2.2018. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed January 4, 2018.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 4, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	01.17.17	11.17
2Q 2018 annual review: added age; added that disease must be recurrent or metastatic per FDA labeling and NCCN compendium; Medicaid line of business added to existing commercial policy; added COC statement for reauth and requirement for positive response to therapy; references reviewed and updated.	01.04.18	05.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.