

Clinical Policy: Gefitinib (Iressa)

Reference Number: CP. PHAR.299

Effective Date: 01.01.17

Last Review Date: 11.17

Line of Business: Medicaid

[Coding Implications](#)
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Gefitinib (Iressa[®]) is a tyrosine kinase inhibitor.

FDA Approved Indication(s)

Iressa is indicated for 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 (which may include office chart notes and lab results) 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 recurrent or metastatic NSCLC;
2. Disease is positive for a sensitizing EGFR mutation (exon 19 deletion or exon 21 [L858R] substitution) as detected by an FDA approved test;
3. Age \geq 18 years;
4. Iressa is prescribed as first-line therapy;
5. Dose does not exceed 250 mg per day (*Note: If Iressa is administered with a strong CYP3A4 inducer [e.g., rifampicin, phenytoin, tricyclic antidepressants], prescribed dose of Iressa does not exceed 500 mg per day*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. If Iressa is requested after disease progression on Iressa, NSCLC is characterized by any of the following (off-label NCCN recommended use):
 - a. Asymptomatic disease (without rapid radiologic progression or threatened organ function);
 - b. Symptomatic brain lesions;
 - c. Isolated symptomatic systemic lesions;
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 per day (*Note: If Iressa is administered with a strong CYP3A4 inducer [e.g., rifampicin, phenytoin, tricyclic antidepressants], prescribed dose of Iressa does not exceed 500 mg 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: 12 months

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 CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – CP. PHAR.57 or evidence of coverage documents.**

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EGFR: epidermal growth factor receptor

FDA: Food and Drug Administration

NSCLC: non-small cell lung cancer

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	250 mg per day	250 mg per day <i>(Note: If Iressa is administered with a strong CYP3A4 inducer [e.g., rifampicin, phenytoin, tricyclic antidepressants], prescribed dose of Iressa does not exceed 500 mg per day).</i>

VI. Product Availability

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Tablets: 250 mg

VII. References

1. Iressa Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2015. Available at: <http://www.azpicentral.com/iressa/iressa.pdf#page=1>. Accessed August 18, 2017.
2. Gefitinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed August 18, 2017.
3. Non-small cell lung cancer (Version 8.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed August 18, 2017.

HCPCS Codes	Description
J8565	Gefitinib, oral, 250 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy.	11.01.16	01.17
Updated references and template. Changed approval duration from 3/6 months to 6/12 months. Updated policy with new safety strategy and added age.	08.18.17	11.17

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

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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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.

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