Clinical Policy: Gefitinib (Iressa)

Reference Number: ERX.SPA.229
Effective Date: 06.01.18
Last Review Date: 05.22
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 tyrosine 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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, advanced, or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent;
5. Disease is positive for a sensitizing EGFR mutation (e.g., exon 19 deletion or insertion; exon 21 point mutation - L858R, L861Q; exon 18 point mutation - G719X; exon 20 point mutation - S768I);
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 250 mg (1 tablet) per day or 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, 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 or 500 mg (2 tablets) per day if receiving a strong CYP3A4 inducer;
   b. New dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 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: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

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

VI. Product Availability

Tablet: 250 mg

VII. References

1. Iressa Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP. May 2021. Available at www.iressa.com. Accessed February 9, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 9, 2022.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 1.2022. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 9, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.04.18	05.18
4Q 2018 annual review: no significant changes; sensitizing EGFR mutations restated as examples per NCCN with related appendix information; references reviewed and updated.	08.07.18	11.18
2Q 2019 annual review: no significant changes; NCCN designation of advanced added to NSCLC; references reviewed and updated.	02.19.19	05.19
2Q 2020 annual review: no significant changes; added Medicaid line of business with 6/12 month initial/continued authorization duration; references reviewed and updated.	02.12.20	05.20
2Q 2021 annual review: no significant changes; references reviewed and updated.	01.14.21	05.21
2Q 2022 annual review: added criterion for use as single-agent therapy for NSCLC; references reviewed and updated.	02.09.22	05.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.