

SPECIALTY GUIDELINE MANAGEMENT

IRESSA (gefitinib) gefitinib

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

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 of Use: Safety and efficacy of Iressa have not been established in patients who have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

B. Compendial Use

EGFR mutation-positive recurrent, advanced, or metastatic NSCLC

All other indications are considered experimental/investigational and not medically necessary.

II. REQUIRED DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: EGFR mutation testing results.

III. CRITERIA FOR INITIAL APPROVAL

Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for treatment of recurrent, advanced, or metastatic NSCLC in members with sensitizing EGFR mutation-positive disease as a single agent.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for EGFR positive NSCLC when either of the following criteria are met:

1. There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
2. Disease is T790M negative and there is no evidence of unacceptable toxicity.

V. REFERENCES

1. Iressa [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2023.
2. Gefitinib [package insert]. Orlando, FL: Ingenus Pharmaceuticals, LLC; April 2023.

Reference number(s)
1660-A

3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc.
Available at: <https://www.nccn.org>. Accessed March 4, 2024.