

Reference number(s)
1660-A

## 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

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1. Iressa [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2023.
2. Gefitinib [package insert]. Orlando, FL: Ingenus Pharmaceuticals, LLC; April 2023.
3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed March 4, 2024.