

# Specialty Guideline Management

## gefitinib-Iressa

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Iressa	gefitinib

### 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.

#### FDA-approved Indication<sup>1,2</sup>

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.

#### Compendial Use<sup>3</sup>

EGFR mutation-positive recurrent, advanced, or metastatic NSCLC

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

## Documentation

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

## Coverage Criteria

### Non-small cell lung cancer (NSCLC)<sup>1-3</sup>

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

## 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:

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

## References

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® © 2025 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed March 3, 2025.