

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Iressa Prior Authorization Policy

- Iressa® (gefitinib tablets – AstraZeneca)

**REVIEW DATE:** 09/08/2021

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### OVERVIEW

Iressa, a tyrosine kinase inhibitor, 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.<sup>1</sup> The 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.

### Guidelines

The National Comprehensive Cancer Network guidelines for NSCLC (version 5.2021 – June 15, 2021) recommend Tagrisso® (osimertinib tablets) as the preferred medication for first-line treatment for patients with *EGFR* mutation-positive (e.g., exon 19 deletion or L858R) NSCLC. Iressa is listed as a recommended first-line treatment (category 1) for these patients. Iressa, among other medications, is also indicated for use in patients with *EGFR* mutation-positive NSCLC when the *EGFR* mutation is discovered during first-line systemic therapy.

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Iressa. All approvals are provided for the duration noted below.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Iressa is recommended in those who meet the following criteria:

#### FDA-Approved Indication

- 1. Non-Small Cell Lung Cancer (NSCLC).** Approve for 3 years if the patient meets the following criteria (A and B):
  - A)** Patient has metastatic NSCLC; AND
  - B)** Patient meets ONE of the following conditions (i or ii):
    - i.** Patient has epidermal growth factor receptor (*EGFR*) exon 19 deletions, as detected by an approved test; OR
    - ii.** Patient has *EGFR* exon 21 (L858R) substitution mutations, as detected by an approved test.

**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Iressa is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**REFERENCES**

1. Iressa® tablets [prescribing information]. Wilmington, DE: AstraZeneca; May 2021.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 5.2021 – June 15, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed August 25, 2021.