Reference number(s)
1660-A

SPECIALTY GUIDELINE MANAGEMENT

IRESSA (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 an indication listed in Section III when there is no evidence of unacceptable toxicity while on the current regimen.

V. REFERENCES

1. Iressa [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2019.

2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed March 1, 2021.