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.

B. Compendial Use
NSCLC

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Non-small cell lung cancer (NSCLC)
Authorization of 12 months may be granted for treatment of NSCLC when the member has a known sensitizing EGFR mutation.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Iressa [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2015.
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed February 27, 2017.
3. The NCCN Clinical Practice Guidelines in Oncology® Non-Small Cell Lung Cancer (Version 4.2017).© 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 27, 2017.