SPECIALTY GUIDELINE MANAGEMENT

TAGRISSO (osimertinib)

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.

FDA-Approved Indication

Tagrisso is indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.

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 metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive NSCLC in members who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy (e.g., erlotinib, afatinib, gefitinib).

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Tagrisso [package insert]. Wilmington, DE: AstraZeneca; September 2016.
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. 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.