Reference number(s)
1663-A

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.

A. FDA-Approved Indications
1. Tagrisso 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 mutations, as detected by an FDA-approved test.
2. 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.
3. Tagrisso is indicated for adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by and FDA approved test.

B. Compendial Uses
1. EGFR mutation-positive recurrent, advanced or metastatic NSCLC.
2. Adjuvant treatment of completely resected stage IB-IIIA EGFR-mutation positive NSCLC.
3. Brain metastases from sensitizing EGFR mutation-positive NSCLC.
4. Brain metastases from EGFR T790M mutation-positive NSCLC.
5. Leptomeningeal metastases from EGFR mutation-positive 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)

A. Authorization of 12 months may be granted for treatment of recurrent, advanced, or metastatic NSCLC (including brain and/or leptomeningeal metastases from NSCLC) in members with sensitizing EGFR mutation-positive disease as a single agent.
B. Authorization of 12 months may be granted for the adjuvant treatment of NSCLC following complete tumor resection in members with EGFR mutation-positive disease as a single agent.

IV. CONTINUATION OF THERAPY

Non-small cell lung cancer (NSCLC)

A. Authorization of 12 months (up to a maximum duration of 3 years) may be granted for continued treatment in members requesting reauthorization for adjuvant treatment of NSCLC when there is no evidence of unacceptable toxicity or disease recurrence while on the current regimen.

B. Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for recurrent, advanced, or metastatic NSCLC when there is no evidence of unacceptable toxicity while on the current regimen.

V. REFERENCES

1. Tagrisso [package insert]. Wilmington, DE: AstraZeneca; December 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 1, 2021.