

Specialty Guideline Management

Tagrisso

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tagrisso	osimertinib

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 Indications¹

- Tagrisso is indicated for the first-line treatment of adult 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.
- Tagrisso is indicated in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- Tagrisso is indicated for the treatment of adult patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.
- 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.

- Tagrisso is indicated for the treatment of adult patients with locally advanced, unresectable (stage III) NSCLC whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

Compendial Uses²

- EGFR mutation-positive recurrent, advanced or metastatic NSCLC.
- Adjuvant treatment of completely resected stage IB-IIIB EGFR-mutation positive NSCLC.
- Brain metastases from EGFR-sensitizing mutation-positive NSCLC.
- Leptomeningeal metastases from EGFR mutation-positive NSCLC.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: EGFR mutation testing results.

Coverage Criteria

Non-Small Cell Lung Cancer (NSCLC)¹⁻²

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 EGFR-sensitizing mutation-positive disease as a single agent or in combination with pemetrexed and either cisplatin or carboplatin.

Authorization of 12 months may be granted for the adjuvant treatment of NSCLC for members with complete tumor resection or node positive NSCLC with EGFR mutation-positive disease as a single agent.

Authorization of 12 months may be granted for consolidation therapy as a single agent for treatment of EGFR mutation-positive unresectable stage II-III NSCLC when there is no disease progression after definitive concurrent chemoradiation.

Continuation of Therapy

Non-Small Cell Lung Cancer (NSCLC)

Reference number(s)
1663-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.

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.

References

1. Tagrisso [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed March 3, 2025.