



PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology (Oral – Epidermal Growth Factor Receptor Inhibitor) Tagrisso Prior Authorization Policy
- Tagrisso® (osimertinib tablets – AstraZeneca)

REVIEW DATE: 02/11/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Tagrisso, a tyrosine kinase inhibitor, is indicated for the following uses:¹

- **Non-Small Cell Lung Cancer (NSCLC) – Epidermal growth factor receptor (EGFR) Mutation-Positive:**
 - First-line treatment of **metastatic NSCLC** tumors that have *EGFR* exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test, in adults.
 - Tagrisso, **in combination with Alimta®** (pemetrexed for intravenous use) **and platinum-based chemotherapy** is indicated for the first-line treatment of locally advanced or metastatic NSCLC that have *EGFR* exon 19 or exon 21 L858R mutations, as detected by an FDA-approved test, in adults.
- **NSCLC – EGFR T790M Mutation-Positive:** Treatment of metastatic *EGFR* T790M mutation-positive NSCLC, as detected by an FDA-approved test, in

adults whose disease has progressed on or after *EGFR* tyrosine kinase inhibitor (TKI) therapy.

- **NSCLC – *EGFR* Mutation-Positive, Post Tumor Resection:** Adjuvant therapy after tumor resection in adults with NSCLC whose tumors have *EGFR* exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- **NSCLC – *EGFR* Mutation-Positive, Unresectable (Stage III) Disease:** Treatment of locally advanced, unresectable (stage III) NSCLC in adults 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.

For adjuvant therapy after tumor resection, Tagrisso prescribing information notes a duration of treatment for a total of 3 years or until disease recurrence or unacceptable toxicity.¹

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for NSCLC (version 3.2026 – December 24, 2025) recommend Tagrisso for the following: Tagrisso can be considered as neoadjuvant therapy in tumors that are positive for *EGFR* exon 19 deletion or L858R mutation-positive if the tumor is deemed resectable after surgical evaluation (category 2A). Tagrisso is recommended for use in patients with *EGFR* (exon 19 deletion, exon 21 L858R) NSCLC who received previous adjuvant chemotherapy or are ineligible to receive platinum-based chemotherapy (category 1). It is also recommended in patients who have previously received Tagrisso for neoadjuvant therapy (category 2A). Tagrisso is recommended for stage IIIA unresectable disease (category 1) after definitive chemoradiation for *EGFR* exon 19 deletion or L858R mutation. A footnote also states that for patients who have received sequential chemoradiation, Imfinzi® (durvalumab intravenous infusion) can be considered, or if *EGFR* exon 19 deletion or L858R, Tagrisso is recommended. NCCN recommends Tagrisso as the “Preferred” first-line treatment for patients with *EGFR* exon 19 deletion or exon 21 (L858R) substitution mutations. Tagrisso can also be used in combination with pemetrexed and either cisplatin or carboplatin in the first-line setting (category 1, “Preferred”). Tagrisso is also a recommended “Preferred” first-line therapy (category 2A) for *EGFR* mutations L861Q, G719X, and S768I. Tagrisso is also recommended as subsequent treatment for all of these mutations. The panel recommends T790M (a secondary mutation in *EGFR*) testing in patients who progress on erlotinib, Gilotrif® (afatinib tablets), gefitinib, or Vizimpro® (dacomitinib tablets). If the patient has *EGFR* T790M-positive metastatic NSCLC, Tagrisso is recommended as subsequent therapy (category 1). If the disease is *EGFR* T790M-negative, the patient can be continued on the current tyrosine kinase inhibitors (i.e., erlotinib, Gilotrif, Iressa, or Vizimpro).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tagrisso. All approvals are provided for the duration noted below.

Tagrisso® (osimertinib tablets – AstraZeneca) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. Non-Small Cell Lung Cancer – Advanced or Metastatic Disease. Approve for 1 year if the patient meets ALL of the following (A, B and C):

A) Patient is \geq 18 years of age; AND

B) Patient meets ONE of the following (i or ii):

i. Patient has epidermal growth factor receptor (*EGFR*) mutation-positive disease; OR

Note: Examples of *EGFR* mutation-positive non-small cell lung cancer include the following: exon 19 deletion, exon 21 (L858R) substitution mutations, L861Q, G719X, and S768I.

ii. Patient meets BOTH of the following (a and b):

a) Patient has epidermal growth factor receptor (*EGFR*) T790M mutation-positive disease; AND

b) Patient has progressed on treatment with at least one of the *EGFR* tyrosine kinase inhibitors.

Note: *EGFR* tyrosine kinase inhibitors are erlotinib, Iressa (gefitinib tablets), Vizimpro (dacomitinib tablets), Gilotrif (afatinib tablets).

2. Non-Small Cell Lung Cancer – Neoadjuvant or Adjuvant Therapy.

Approve for a total of 3 years if the patient meets ALL of the following (A, B, C, and D):

A) Patient is \geq 18 years of age; AND

B) Patient has resectable disease; AND

C) Patient has *EGFR* exon 19 deletion or exon 21 (L858R) substitution mutation; AND

D) Patient has Stage IB, Stage II, or Stage III disease and meets ONE of the following (i or ii):

i. The medication will be used as neoadjuvant therapy; OR

ii. The medication will be used as adjuvant therapy and meets ONE of the following (a, b, or c):

a) Patient had received previous adjuvant chemotherapy; OR

b) Patient is ineligible to receive platinum-based chemotherapy; OR

c) The medication was used previously as neoadjuvant therapy.

3. Non-Small Cell Lung Cancer – Unresectable, Stage III. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

A) Patient is \geq 18 years of age; AND

B) Patient has locally advanced, unresectable (stage III) disease; AND

C) Patient has *EGFR* exon 19 deletions or exon 21 (L858R) substitution mutation; AND

D) Patient has not had disease progression during or following platinum-based chemoradiation therapy.

Note: Patient could have received concurrent or sequential chemoradiation therapy.

CONDITIONS NOT COVERED

Tagrisso® (osimertinib tablets – AstraZeneca) is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available):

REFERENCES

1. Tagrisso® tablets [prescribing information]. Wilmington, DE: AstraZeneca; September 2024
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2026 – December 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 7, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Non-Small Cell Lung Cancer: Deleted the word “sensitizing” in reference to EGFR mutations. This verbiage is no longer used in the guidelines.	01/31/2024
Update	03/11/2024: No criteria changes. Updated Overview section with new indication for Tagrisso. Also updated Guidelines section.	NA
Selected Revision	Non-Small Cell Lung Cancer – Unresectable, Stage III. Added new approval condition and criteria based on new indication.	10/16/2024
Annual Revision	Non-Small Cell Lung Cancer – Advanced or Metastatic Disease: Added qualifier “Advanced or Metastatic Disease” to indication. Deleted criterion “patient has advanced or metastatic disease” since it is now addressed in the indication. Non-Small Cell Lung Cancer – Post Tumor Resection Adjuvant Therapy: Added qualifier “Adjuvant Therapy” to the indication. Approval duration was changed from 1 year to a “total of 3 years” based on the label.	02/05/2025
Update	04/21/2025: The policy name was changed from “Oncology – Tagrisso PA Policy” to “Oncology (Oral – Epidermal Growth Factor Receptor Inhibitor) – Tagrisso PA Policy”.	N/A
Annual Revision	Non-Small Cell Lung Cancer – Advanced or Metastatic Disease: In reference to EGFR mutation-positive disease and EGFR T790M mutation-positive disease, the requirement that the mutation was detected by an approved test was removed. Non-Small Cell Lung Cancer – Neoadjuvant or Adjuvant Therapy: The approval indication was modified as noted. Previously the indication was “Non-Small Cell Lung Cancer – Post-Tumor Resection Adjuvant Therapy”. For requirement referring to patient has completely resected disease was changed to “Patient has resectable disease”. Patient has Stage IB, Stage II, or Stage III disease was added as a requirement along with options to approve for neoadjuvant therapy or adjuvant therapy. For adjuvant therapy, an option for approval was added if the medication was previously used for neoadjuvant therapy.	02/11/2026

	Non-Small Cell Lung Cancer – Unresectable, Stage III: In reference to EGFR exon 19 deletions or exon 21 (L858R) substitution mutation, the requirement that the mutation was detected by an approved test was removed.	
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