PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Tagrisso Prior Authorization Policy
- Tagrisso® (osimertinib tablets – AstraZeneca)

REVIEW DATE: 01/31/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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 rector (*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.
- **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.

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for NSCLC (version 1.2024 – December 21, 2023) recommend testing for *EGFR* mutations in patients with metastatic disease.[2] The most common *EGFR* mutations are exon 19 deletion and exon 21 (L858R) substitution mutations. Other less common mutations that are

also responsive to *EGFR* tyrosine kinase inhibitors (TKIs) include L861Q, G719X, and S768I. 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 Alimta® (pemetrexed for injection) and either cisplatin or carboplatin in the first-line setting (category 2A, "Other Recommended" regimens). 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 tablets, Gilotrif® (afatinib tablets), Iressa® (gefitinib tablets), 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 TKI (i.e., erlotinib, Gilotrif, Iressa, or Vizimpro). Tagrisso is also recommended for use in patients with completely resected stage IB-IIIA *EGFR* (exon 19 deletion, L858R) NSCLC who received previous adjuvant chemotherapy or are ineligible to receive platinum-based chemotherapy.

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.** Approve for 1 year if the patient meets the following (A, B and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has advanced or metastatic disease; AND
   - **C)** Patient meets one of the following (i or ii):
     - **i.** Patient has epidermal growth factor receptor (*EGFR)* mutation-positive disease as detected by an approved test; 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 as detected by an approved test; 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 – Post Tumor Resection.** Approve for 1 year if the patient meets the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has completely resected disease; AND
   C) Patient has *EGFR* exon 19 deletion or exon 21 (L858R) substitution mutation as detected by an approved test; AND
   D) Patient meets one of the following (i or ii):
      i. Patient received previous adjuvant chemotherapy; OR
      ii. Patient is ineligible to receive platinum-based chemotherapy.

CONDITIONS NOT COVERED

- **Tagrisso® (osimertinib tablets – AstraZeneca)**

is(are) considered experimental, investigational or unproven 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 2022
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 23, 2024

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Non-Small Cell Lung Cancer:** Criteria for Epidermal Growth Factor Receptor (*EGFR*) Mutation-Positive (Other than *EGFR* T790M-positive mutation) AND Epidermal Growth Factor (*EGFR*) T790M Mutation-Positive are combined into one set of criteria. There was one change to the criterion: previously for T790 mutation-positive disease, the criterion approved if patient has metastatic disease, now, the criterion will approve if the patient has advanced or metastatic disease. **Non-Small Cell Lung Cancer- Post Tumor Resection:** Added the word "tumor" to criteria set; previously it read "Post Resection."	01/11/2023
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