PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 01/31/2024

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.
  - 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.

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for NSCLC (version 3.2024 – March 12, 2024) 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 1, "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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tagrisso is recommended in those who meet one of the following criteria:

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 RECOMMENDED FOR APPROVAL

Coverage of Tagrisso is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tagrisso™ tablets [prescribing information]. Wilmington, DE: AstraZeneca; February 2024
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2024 – March 12, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 12, 2024.