VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 01/06/2021

OVERVIEW

Tagrisso, a kinase inhibitor, is indicated for the treatment of adult patients for the following uses:[1]

- **Non-small cell lung cancer (NSCLC)**, with metastatic epidermal growth factor receptor (*EGFR*) T790M mutation-positive disease, as detected by an FDA-approved test. It is specifically approved for patients who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy (EGFR-TKI).
- **NSCLC**, first-line treatment of patients with metastatic NSCLC whose tumors have *EGFR* exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- **NSCLC**, adjuvant therapy after tumor resection in tumors that have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for NSCLC (version 2.2021 – December 15, 2020) recommend *EGFR* mutation testing in patients with nonsquamous NSCLC (i.e., adenocarcinoma, large cell, NSCLC not otherwise specified [NOS]) and squamous cell NSCLC.[2] Tagrisso is recommended for consideration in patients who have been treated with previous adjuvant chemotherapy or ineligible for platinum-based chemotherapy in stage IB-IIIA *EGFR* mutation-positive disease after complete resection (category 2A). For advanced or metastatic disease, erlotinib, Iressa® (gefitinib tablets), Gilotrif™ (afatinib tablets), Vizimpro® (dacomitinib tablets), and Tagrisso (all category 1) are all recommended for the first-line treatment of patients with sensitizing *EGFR*-mutation positive NSCLC. Tagrisso is noted as the "preferred" first-line option by NCCN. Upon disease progression, T790M testing is recommended in guidelines. For systemic multiple lesions that are T790M mutation-positive, Tagrisso, if not previously given, is the category 1 recommended option. If T790M mutation-negative, initial cytotoxic therapy options listed for adenocarcinoma, or squamous cell carcinoma (e.g., doublet chemotherapy) can be considered in this setting (category 2A). NCCN notes that in patients with actionable mutations. Immunotherapy is less effective in the second-line setting, irrespective of PD-L1 expression.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tagrisso. All approvals are provided for 3 years in duration unless otherwise noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Non-Small Cell Lung Cancer (NSCLC) – Epidermal Growth Factor Receptor (*EGFR*) Mutation-Positive.** Approve if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following criteria (i, ii, or iii):
     - **i.** Approve for up to 3 years (total) if the patient meets BOTH of the following criteria (a and b):
       - **a)** The medication is used as adjuvant therapy after tumor resection; AND
       - **b)** The tumor is positive for *EGFR* exon 19 deletions or exon 21 L858R mutations, as detected by an approved test; OR
     - **ii.** Approve for 3 years if the patient meets BOTH of the following criteria (a and b):
       - **a)** Patient has metastatic *EGFR* T790M mutation-positive NSCLC as detected by an approved test; AND
       - **b)** Patient has progressed on one of the EGFR-tyrosine kinase inhibitors; OR
         Note: Examples are erlotinib , Iressa® [gefitinib tablets], Vizimpro® [dacomitinib tablets], Gilotrif® [afatinib tablets]; OR
     - **iii.** Approve for 3 years if the patient meets ONE of the following criteria (a or b):
       - **a)** Patient has metastatic disease with *EGFR* exon 19 deletions as detected by an approved test; OR
       - **b)** Patient has metastatic disease with *EGFR* exon 21 L858R mutations as detected by an approved test.

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 Pharmaceuticals LP; December 2020.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 2.2021 – December 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on December 23, 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
Selected Revision	Moved approval criteria for use in first-line setting for exon 19 or exon 21 mutations to under FDA-approved use due to new indication approval. Deleted "advanced or" from first-line setting use.	04/25/2018
Annual Revision	Criteria modified for T790M mutation where the list of agents is replaced with "one of the EGFR-tyrosine kinase inhibitors". The agents are listed as examples. Vizimpro was added to this list.	12/19/2018
Annual Revision	No criteria changes.	12/18/2019
Annual Revision	**Non-Small Cell Lung Cancer:** Added age requirement. Added new approval criteria for up to 3 years for Tagrisso use as adjuvant therapy based on FDA-approval. Moved examples of EGFR tyrosine kinase inhibitors to Note.	01/06/2021

EGFR – Epidermal growth factor receptor.