



PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Tagrisso® (osimertinib tablets – AstraZeneca)

TAC APPROVAL DATE: 12/19/2018

OVERVIEW

Tagrisso, a kinase inhibitor, is indicated for the treatment of patients with metastatic epidermal growth factor receptor (*EGFR*) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test.¹ It is specifically approved for patients who have progressed on or after *EGFR* tyrosine kinase inhibitor (TKI) therapy (*EGFR*-TKI). Tagrisso is also indicated for the 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.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for NSCLC (version 2.2019) recommend *EGFR* mutation testing in patients with nonsquamous NSCLC (i.e., adenocarcinoma, large cell) or in NSCLC not otherwise specified (NOS).² Tarceva® (erlotinib tablets), 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 added a footnote to this recommendation to also consider Gilotrif and Erbitux® (cetuximab for injection) combination regimen in patients with disease progression (T790M-negative multiple systemic lesions) on *EGFR*-TKI therapy (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 for 3 years if the patient meets ONE of the following criteria (A or B):
 - A) The patient meets BOTH of the following criteria (i and ii):**
 - i.** The patient has metastatic *EGFR* T790M mutation-positive NSCLC as detected by an approved test; **AND**
 - ii.** The patient has progressed on one of the EGFR-tyrosine kinase inhibitors (e.g., Tarceva® [erlotinib tablets], Iressa® [gefitinib tablets], Vizimpro® [dacomitinib tablets], Gilotrif® [afatinib tablets]); **OR**
 - B) The patient has metastatic NSCLC and meets ONE of the following criteria (i or ii):**
 - i.** The patient has *EGFR* exon 19 deletions as detected by an approved test; **OR**
 - ii.** The patient has *EGFR* exon 21 L858R mutations as detected by an approved test.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Tagrisso has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

- 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; April 2018.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 2.2018 – November 21, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on December 14, 2018.

HISTORY

Type of Revision	Summary of Changes*	TAC/DEU Approval Date
New Policy	--	12/16/2015
Annual revision	No criteria changes	12/07/2016
Annual revision	Added approval criteria for Tagrisso use in first-line setting in patients with exon 19 deletion or exon 21 substitution mutation based on NCCN guidelines.	11/29/2017
DEU revision	Re-formatted to separate out approval criteria in first-line setting (previously criteria 1B) to Other Uses with Supportive Evidence.	01/17/2018
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

TAC – Therapeutic Assessment Committee; * For a further summary of criteria changes, refer to respective TAC minutes available at: <http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>.