UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Tagrisso

Program	Prior Authorization
Medication	Tagrisso™ (osimertinib)
Issue Date	8/2016
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

1. Background:

Tagrisso (osimertinib) is a kinase inhibitor 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, who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.[1] The National Cancer Comprehensive Network (NCCN) also recommends the use of Tagrisso for the treatment for recurrent central nervous system cancers if Tagrisso is active against the primary tumor (EGFR T790M mutation-positive non-small cell lung cancer) and as first-line or subsequent therapy for disease positive for a sensitizing EGRF mutation.

2. Coverage Criteria:

A. Central Nervous System (CNS) Cancer

1. Initial Authorization

a. **Tagrisso** will be approved based on **all** of the following criteria:

(1) Diagnosis of CNS Cancer

-AND-

(2) Disease is recurrent

-AND-

(3) Primary disease (tumor) is responsive to Tagrisso therapy (e.g., EGFR T790M mutation-positive NSCLC)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Tagrisso** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Tagrisso therapy

Authorization will be issued for 12 months.

B. Non-Small Cell Lung Cancer (NSCLC)

1. Initial Authorization

a. **Tagrisso** will be approved based on **all** of the following criteria:

(1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-

(2) Disease is **one** of the following:

(a) Recurrent
(b) Metastatic

-AND-

(3) **One** of the following:

(a) **Both** of the following:

i. Disease is sensitizing EGRF mutation positive
ii. Used as a first-line therapy

-OR-

(b) **Both** of the following:

i. Disease is sensitizing EGRF mutation positive
ii. Subsequent therapy for disease that has progressed while on Tagrisso therapy

-OR-

(c) **Both** of the following:

i. Disease is epidermal growth factor receptor (EGFR) T790M mutation-positive

-AND-

ii. History of failure, contraindication, or intolerance to prior EGFR tyrosine kinase inhibitor (TKI) therapy [e.g., Tarceva (erlotinib), Gilotrif (afatinib), Iressa (gefitinib)]

Authorization will be issued for 12 months.

2. Reauthorization

a. **Tagrisso** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tagrisso therapy

Authorization will be issued for 12 months.

3. References:

1. Tagrisso [package insert]. AstraZeneca Pharmaceuticals LP: Wilmington, DE; March 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed October 11, 2017.

Program	Prior Authorization –Tagrisso (osimertinib)
Change Control	
Date	Change
8/2016	New Program
12/2016	Annual review. Added Iressa (gefitinib) to examples of TKI therapy, with no significant changes to clinical criteria. Updated references.
11/2017	Updated background and references. Added coverage criteria for CNS cancer. Revised coverage criteria for NSCLC.