UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Tagrisso

Program	Prior Authorization
Medication	Tagrisso® (osimertinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	8/2016
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

1. Background:

Tagrisso (osimertinib) is a kinase inhibitor indicated for first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, and patients with metastatic EGFR T790M mutation-positive (NSCLC), 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 EGFR mutation.

2. Coverage Criteria:

A. <u>Central Nervous System (CNS) Cancer</u>

1. <u>Initial Authorization</u>

a. **Tagrisso** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of CNS Cancer

-AND-

(3) Primary disease (tumor) is responsive to Tagrisso therapy (e.g., EGFR T790M mutation, exon 19 deletions, or exon 21 L858R 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) Advanced
(c) Metastatic

-AND-

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

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

i. Disease is sensitizing EGFR mutation positive (e.g., EGFR T790M mutation, exon 19 deletions, or exon 21 L858R mutation-positive)
ii. Used as a first-line therapy

-OR-

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

i. Disease is sensitizing EGFR mutation positive (e.g., EGFR T790M mutation, exon 19 deletions, or exon 21 L858R 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

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.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Tagrisso** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

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.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Tagrisso [package insert]. AstraZeneca Pharmaceuticals LP: Wilmington, DE; June 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed October 5, 2020.

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.
11/2018	Clarified EGFR mutation positive. Added NCCN Recommended Regimen review criteria. Updated background and references.
11/2019	Added “advanced” disease to criteria for NSCLC. Updated references.
11/2020	Annual review. Updated coverage rationale according to NCCN guidelines. Updated background and references. Added Additional Clinical Rules section.