UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1174-9
Program	Prior Authorization/Notification
Medication	Tagrisso® (osimertinib)
P&T Approval Date	1/2016, 12/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, 11/2022, 11/2023
Effective Date	2/1/2024

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, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy. Tagrisso is also indicated for adjuvant therapy after tumor resection in adults with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations. The National Cancer Comprehensive Network (NCCN) recommends the use of Tagrisso for the treatment for limited and extensive brain metastases in EGFR mutation-positive NSCLC. NCCN also recommends Tagrisso for use in leptomeningeal metastases from NSCLC that is EGFR mutation-positive.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. Central Nervous System (CNS) Cancer

1. **Initial Authorization**

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

      (1) Diagnosis of **one** of the following CNS Cancers:

         (a) Limited brain metastases from non-small cell lung cancer

-OR-

(b) Extensive brain metastases from non-small cell lung cancer

-OR-

(c) Leptomeningeal metastases from non-small cell lung cancer

-AND-

(2) 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.

C. 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) **One** of the following:

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

i. Disease is recurrent, advanced, or metastatic
ii. Disease is sensitizing EGFR mutation positive (e.g., EGFR T790M mutation, exon 19 deletions, exon 21 L858R, S768I, L861Q, or G719X mutation-positive)
iii. Used as a first-line therapy

-OR-

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

i. Disease is recurrent, advanced, or metastatic
ii. Disease is sensitizing EGFR mutation positive (e.g., EGFR T790M

mutation, positive exon 19 deletions, exon 21 L858R, S768I, L861Q, or G719X mutation-positive)
iii. Subsequent therapy for disease that has progressed while on Tagrisso therapy

-OR-

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

i. Disease is recurrent, advanced, or metastatic
ii. Disease is epidermal growth factor receptor (EGFR) T790M mutation-positive
iii. History of failure, contraindication, or intolerance to prior EGFR tyrosine kinase inhibitor (TKI) therapy [e.g., Tarceva (erlotinib), Gilotrif (afatinib), Iressa (gefitinib)]

-OR-

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

i. Disease is EGFR exon 19 deletion or exon 21 L858R mutation positive
ii. Used as adjuvant therapy after tumor resection

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.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed September 21, 2023.

Program	Prior Authorization/Notification – Tagrisso (osimertinib)
Change Control	
1/2016	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	Annual review. Update background and references. Added coverage criteria for CNS cancer. Revised coverage criteria for NSCLC.
11/2018	Annual review. Updated coverage rationale. Updated background and references.
11/2019	Annual review. Updated coverage rationale. Added NCCN recommended regimens criteria. Updated references.
11/2020	Annual review. Updated coverage rationale according to NCCN guidelines. Updated background and references.
11/2021	Annual review. Updated coverage rationale for new treatment indication. Updated background and references.
11/2022	Annual review. Added EGFR S768I, L861Q, and G719X mutation positive tumors as examples under coverage criteria for non-small cell lung cancer per NCCN guidelines. Updated background, added state mandate, and updated references.
11/2023	Annual review. Updated background. Updated NSCLC criteria per FDA label. Updated CNS cancers per NCCN recommendation. Updated references.