Commercial PA Criteria

Effective: March 10th, 2016

Prior Authorization: Tagrisso

Products Affected: Tagrisso (Osimertinib) 40 mg tablet, Tagrisso (Osimertinib) 80 mg tablet,

Medication Description:
Osimertinib is an irreversible epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor which binds to select mutant forms of EGFR, including T790M, L858R, and exon 19 deletion at lower concentrations than wild-type. Osimertinib exhibits less activity against wild-type EGFR (as compared to other EGFR inhibitors) and is selective for sensitizing mutations and the T790M resistance mutation, which is the most common mechanism of resistance to EGFR tyrosine kinase inhibitors.

Covered Uses:

1. **Non-Small Cell Lung Cancer (NSCLC) – Epidermal growth factor rector (*EGFR*) Mutation-Positive:** First-line treatment of metastatic NSCLC tumors that have *EGFR* exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test, in adults.
    - Tagrisso, **in combination with Alimta** (pemetrexed for intravenous use) **and platinum-based chemotherapy** is indicated for the first-line treatment of locally advanced or metastatic NSCLC that have EGFR exon 19 or exon 21 L858R mutations, as detected by an FDA-approved test, in adults.
2. **NSCLC – *EGFR* T790M Mutation-Positive:** Treatment of metastatic *EGFR* T790M mutation-positive NSCLC, as detected by an FDA-approved test, in adults whose disease has progressed on or after *EGFR* tyrosine kinase inhibitor (TKI) therapy.
3. **NSCLC – *EGFR* Mutation-Positive, Post Tumor Resection:** Adjuvant therapy after tumor resection in adults with NSCLC whose tumors have *EGFR* exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
4. **NSCLC – *EGFR* Mutation-Positive, Unresectable (Stage III) Disease:** Treatment of locally advanced, unresectable (stage III) NSCLC in adults whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have *EGFR* exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

Exclusion Criteria: N/A

Required Medical Information:

1. Confirmed T790M mutation-positive NSCLC as detected by an approved test
2. Previous/current treatment regimen
3. Dose and frequency

Age Restrictions: None

Prescriber Restrictions: None
Coverage Duration: 1 yea
Other Criteria:

1. **Non-Small Cell Lung Cancer**. Approve for 1 year if the patient meets the following (A, B, **AND** C)

A. Patient is ≥ 18 years of age; **AND**
B. Patient has advanced or metastatic disease; AND
C. Patient meets one of the following (I **or** ii):
   i. Patient has epidermal growth factor receptor (*EGFR)* mutation-positive disease as detected by an approved test; **OR**
   Note: Examples of EGFR mutation-positive non-small cell lung cancer include the following: exon 19 deletion, exon 21 (L858R) substitution mutations, L861Q, G719X, and S768I.
   ii. Patient meets BOTH of the following (a **and** b):
      a) Patient has epidermal growth factor receptor (*EGFR*) T790M mutation-positive disease as detected by an approved test; **AND**
      b) Patient has progressed on treatment with at least one of the *EGFR* tyrosine kinase inhibitors.
      Note: *EGFR* tyrosine kinase inhibitors are erlotinib, Iressa (gefitinib tablets), Vizimpro (dacomitinib tablets), Gilotrif (afatinib tablets).

2. **Non-Small Cell Lung Cancer – Post Tumor Resection.** Approve for 1 year if the patient meets the following (A, B, C, **and** D):
   A. Patient is ≥ 18 years of age; **AND**
   B. Patient has completely resected disease; **AND**
   C. Patient has *EGFR* exon 19 deletion or exon 21 (L858R) substitution mutation as detected by an approved test; **AND**
   D. Patient meets one of the following (I **or** ii):
      i. Patient received previous adjuvant chemotherapy; **OR**
      ii. Patient is ineligible to receive platinum-based chemotherapy.

3. **Non-Small Cell Lung Cancer – Unresectable, Stage III.** Approve for 1 year if the patient meets ALL of the following (A, B, C, **and** D):
   A. Patient is ≥ 18 years of age; **AND**
   B. Patient has locally advanced, unresectable (stage III) disease; **AND**
   C. Patient has *EGFR* exon 19 deletions or exon 21 (L858R) substitution mutation as detected by an approved test; **AND**
   D. Patient has not had disease progression during or following platinum-based chemoradiation therapy.
   Note: Patient could have received concurrent or sequential chemoradiation therapy.

References:

1. Tagrisso™ tablets [prescribing information]. Wilmington, DE: AstraZeneca; September 2024
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 10.2024 – September 23, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 14, 2024.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	03/10/2016
2	Policy Update	Updated Indications to match FDA Label	Medication Description, Exclusion Criteria, Other Criteria	6/18/2019
3	Update	Removal of Tagrisso from CCI Oncology Policy, adoption of EH Tagrisso Policy	All	6/25/2019
4	Update	Added continuation coverage duration of 3 years	Coverage Duration	7/1/2019
5	Update	Updated Indications to match to FDA labeled uses. Addition of NSCLC – *EGFR* Mutation-Positive, Unresectable (Stage III) Disease	Medication Description, Covered Uses, Exclusion Criteria, Other Criteria	10/30/2024