



Commercial/Healthcare Exchange PA Criteria

Effective: March 10th, 2016 (EH)

Prior Authorization: Tagrisso

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

Medication Description:

Osimertinib is indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) mutation-positive non-small cell lung cancer (NSCLC): either as first-line therapy in patients with exon 19 deletions or exon 21 (L858R) substitution mutations, or after progression on EGFR tyrosine kinase inhibitor (TKI) therapy in patients with T790M mutation.

Covered Uses:

1. Non-Small Cell Lung Cancer (NSCLC)

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:

Initial: 12 Months

Continuation: 3 years

Other Criteria:

1. Non-Small Cell Lung Cancer (NSCLC).

A) The patient has metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive NSCLC as detected by an approved test; **AND** the patient has progressed on or after one of Tarceva® (erlotinib tablets), Iressa® (gefitinib tablets), or Gilotrif® (afatinib tablets) therapy

OR

B) Tagrisso will be used to treat metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

References:

1. Product Information: TAGRISSO(R) oral tablets, osimertinib oral tablets. AstraZeneca Pharmaceuticals LP (per manufacturer), Wilmington, DE, 2018.

Last Res. July 1st, 2019



Confidential Information

This document is confidential and proprietary to ConnectiCare. Unauthorized use and distribution are prohibited.

2. Tagrisso™ tablets [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2015.
3. Tagrisso – use in patients with EGFR T790M mutation positive NSCLC. AstraZeneca. Received November 16, 2015.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 2.2016). © 2015 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on November 24, 2015.

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