

## Tagrisso™ (osimertinib) (Oral)

Document Number: IC-0259

Last Review Date: 05/01/2018

Date of Origin: 12/04/2015

Dates Reviewed: 12/2015, 04/2016, 04/2017, 04/2018, 05/2018

### I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 80 mg tablets: 1 tablet per day

#### B. Max Units (per dose and over time) [Medical Benefit]:

- 80 mg daily

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**
- Must be used as single agent; **AND**
- Patient's tumor is epidermal growth factor receptor (EGFR) mutation-positive, confirmed by an FDA-approved test (i.e. COBAS EGFR Mutation Test); **AND**

#### Non-small cell lung cancer †

- Patient's disease is metastatic; **AND**
  - Must be used as subsequent therapy, for T790M mutation-positive disease, after progression on or after EGFR tyrosine kinase inhibitor therapy (e.g., erlotinib, gefitinib, afatinib, etc.); **OR**
  - Used as first-line therapy; **OR**
  - Continuation of therapy following disease progression on osimertinib (Tagrisso) for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions.

#### Central Nervous System- Brain Metastases ‡

- Patient has brain metastases from T790M mutation-positive NSCLC; **AND**

- Patient’s disease is recurrent; **AND**
- Patient has stable systemic disease.

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

#### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria in Section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: interstitial lung disease (ILD); QTc prolongation; cardiomyopathy (cardiac failure, congestive heart failure, pulmonary edema or decreased ejection fraction); keratitis, etc.

#### V. Dosage/Administration

Indication	Dose
Non-small cell lung cancer	80 mg tablet orally once daily
CNS-Metastatic Lesions	80 mg tablet orally once daily

#### VI. Billing Code/Availability Information

Jcode:

- J8999 – Prescription drug, oral, chemotherapeutic, nos
- C9399– Unclassified drugs or biologicals, (Hospital Outpatient Use ONLY)

NDC:

- 40 mg tablet: 00310-1349-xx
- 80 mg tablet: 00310-1350-xx

#### VII. References

1. Tagrisso [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; April 2018. Accessed April 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) osimertinib. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most

recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2018.

- Goss G, Tsai C.M., Shepherd F, et al. MA16.11 CNS Response to Osimertinib in Patients with T790M-Positive Advanced NSCLC: Pooled Data from Two Phase II Trials. *Journal of Thoracic Oncology*, Volume 12, Issue 1, S440 - S441.

## Appendix 1 – Covered Diagnosis Codes

ICD-10 Codes	Diagnosis
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C79.31	Secondary malignant neoplasm of brain
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

**Medicare Part B Administrative Contractor (MAC) Jurisdictions**

<b>Jurisdiction</b>	<b>Applicable State/US Territory</b>	<b>Contractor</b>
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC