Tagrisso® (osimertinib)
(Oral)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed (unless otherwise specified).

- Adjuvant treatment of NSCLC can be authorized up to a maximum of 3 years of therapy.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 40 mg tablets: 1 tablets per day
- 80 mg tablets: 2 tablets per day

B. Max Units (per dose and over time) [HCPCS Unit]:

CNS Cancers Leptomeningeal Metastases from NSCLC:

- 160 mg daily

All other indications:

- 80 mg daily

III. Initial Approval Criteria [1,2]

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**

Universal Criteria

- Must be used as single agent; **AND**
- Patient's tumor is epidermal growth factor receptor (EGFR) mutation-positive, confirmed by an FDA-approved or CLIA-compliant test❖; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
  - Coadministration with drugs known to prolong the QTc interval with known risk of Torsades de pointes (e.g. amiodarone, citalopram, fluconazole, clarithromycin, etc.); **AND**

Non-Small Cell Lung Cancer (NSCLC) † Φ [1,2,4,5,7]

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- Used for recurrent, advanced or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **OR**
  - Used as continuation of therapy following disease progression on osimertinib for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions; **OR**
  - Used as subsequent therapy for T790M mutation-positive disease after progression on or after EGFR tyrosine kinase inhibitor therapy (e.g., erlotinib, gefitinib, afatinib, dacomitinib, etc.); **OR**
  - Used for the treatment of progressive CNS disease or leptomeningeal disease following progression on EGFR tyrosine kinase inhibitor therapy (e.g., erlotinib, gefitinib, afatinib, dacomitinib, etc.); **OR**
- Used in adjuvant therapy after tumor resection

Central Nervous System Cancers – Brain Metastases ‡ [1,2,3,6]

- Patient has brain metastases from T790M mutation-positive Non-Small Cell Lung Cancer; **AND**
  - Used as initial treatment in patients with small asymptomatic limited or extensive brain metastases; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
- Patient has leptomeningeal metastases from EGFR mutation-positive Non-Small Cell Lung Cancer; **AND**
  - Used as primary treatment for patients with good risk status (e.g., KPS ≥60, no major neurologic deficits, minimal systemic disease, and reasonable systemic treatment options if needed); **OR**
  - Used as maintenance treatment in patients with negative CSF cytology or in clinically stable patients with persistently positive CSF cytology; **OR**
  - Used in patients with positive CSF cytology that have disease progression after prior treatment

❖ *If confirmed using an immunotherapy assay-http://www.fda.gov/companiondiagnostics*

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

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IV. Renewal Criteria [1,2]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by 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)/pneumonitis, QTc interval prolongation, cardiomyopathy (cardiac failure, congestive heart failure, pulmonary edema, or decreased ejection fraction), keratitis, erythema multiforme/ Stevens-Johnson syndrome, cutaneous vasculitis, etc.

V. Dosage/Administration [1,3.6]

Indication	Dose
Non-small cell lung cancer (NSCLC)	Advanced, recurrent, or metastatic disease: 80 mg orally once daily until disease progression or unacceptable toxicity Adjuvant therapy: 80 mg orally once daily until disease recurrence or unacceptable toxicity, up to a maximum of 3 years of therapy
CNS Cancers – Limited and Extensive Brain Metastases from NSCLC	80 mg orally once daily
CNS Cancers Leptomeningeal Metastases from NSCLC	160 mg orally once daily

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic, nos

NDC:

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

VII. References

1. Tagrisso [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; December 2020. Accessed December 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) osimertinib. National Comprehensive Cancer Network, 2020. 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

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recent and complete version of the Compendium, go online to NCCN.org. Accessed December 2020.
3. 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.
4. Soria JC, Ohe Y, Vansteenkiste J, et al. Osimertinib in Untreated EGFR-Mutated Advanced Non-Small-Cell Lung Cancer. N Engl J Med. 2018 Jan 11;378(2):113-125. doi: 10.1056/NEJMoa1713137. Epub 2017 Nov 18.
5. Mok TS, Wu Y-L, Ahn M-J, et al. Osimertinib or Platinum-Pemetrexed in EGFR T790M-Positive Lung Cancer. N Engl J Med. 2017 Feb 16;376(7):629-640. doi: 10.1056/NEJMoa1612674. Epub 2016 Dec 6.
6. Yang JCH, Cho BC, Kim DW, et al. Osimertinib for patients (pts) with leptomeningeal metastases (LM) from EGFR-mutant non-small cell lung cancer (NSCLC): Updated results from the BLOOM study. J Clin Oncol 35, 2017 (suppl; abstr 2020). 10.1200/JCO.2017.35.15_suppl.2020.
7. Wu YL, Tsuboi M, He J, et al. Osimertinib in Resected EGFR-Mutated Non-Small-Cell Lung Cancer. N Engl J Med. 2020 Oct 29;383(18):1711-1723. doi: 10.1056/NEJMoa2027071.

Appendix 1 – Covered Diagnosis Codes

ICD-10 Codes	Description
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
C79.32	Secondary malignant neoplasm of cerebral meninges
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

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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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) 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/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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

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