

Tagrisso (osimertinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Tagrisso (osimertinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Tagrisso (osimertinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Non-Small Cell Lung cancer (NSCLC); **AND**
- II. Individual has tumors with EGFR exon 19 deletions, G719X, L861Q, S768I, or exon 21 L858R mutations, with test results are confirmed;

OR

- III. Individual has a diagnosis of recurrent, advanced, or metastatic Non-Small Cell Lung cancer (NSCLC) with EGFR (epidermal growth factor receptor) T790M mutation present with test results confirmed;
AND
- IV. Individual has progressed on or after EGFR tyrosine kinase inhibitor therapy (such as afatinib, gefitinib, erlotinib);

OR

- V. Individual has a diagnosis of metastatic NSCLC with asymptomatic, recurrent, or relapsed brain metastases (NCCN 2A); **AND**
 - A. Primary NSCLC that is EGFR mutation-positive; **OR**
 - B. Individual has leptomeningeal metastases from primary NSCLC that is EGFR mutation-positive.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 29, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed March 29, 2023.
6. Non-Small Cell Lung Cancer. V2.2023. Revised February 17, 2023.
7. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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