

| Market Applicability | | | | | | | |
|----------------------|----|----|----|----|----|----|----|
| Market | DC | GA | KY | MD | NJ | NY | WA |
| Applicable | X | X | X | X | X | X | X |

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 Metastatic Non-Small Cell Lung cancer (NSCLC); **AND**
- II. Individual has tumors with EGFR exon 19 deletions or exon 21 L858R mutations, with test results are confirmed;

OR

- III. Individual has a diagnosis of 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**
- VI. Primary NSCLC has an EGFR T790M mutation.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 18, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed April 2020.
 - a. Non-Small Cell Lung Cancer. V3.2020. Revised February 11, 2020.
 - b. Central Nervous System Cancers. V1.2020. Revised March 10, 2020.

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