Mass General Brigham
Health Plan

# Tagrisso (osimertinib)
# Effective 05/01/2022

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| **Plan** | ☐ MassHealth UPPL<br>☒ Commercial/Exchange | **Program Type** | ☒ Prior Authorization<br>☐ Quantity Limit<br>☐ Step Therapy |
| **Benefit** | ☒ Pharmacy Benefit<br>☐ Medical Benefit | | |
| **Specialty Limitations** | This medication has been designated specialty and must be filled at a contracted specialty pharmacy. | | |
| **Contact Information** | **Medical and Specialty Medications**<br>All Plans \| Phone: 877-519-1908 \| Fax: 855-540-3693 | | |
| | **Non-Specialty Medications**<br>All Plans \| Phone: 800-711-4555 \| Fax: 844-403-1029 | | |
| **Exceptions** | N/A | | |

**Overview**
Osimertinib is an irreversible epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor which binds to select mutant forms of EGFR, including T790M, L858R, and exon 19 deletion at lower concentrations than wild-type. Osimertinib exhibits less activity against wild-type EGFR (as compared to other EGFT inhibitors) and is selective for sensitizing mutations and the T790M resistance mutation, which is the most common mechanism of resistance to EGFR tyrosine kinase inhibitors

**Coverage Guidelines**
Authorization will be granted for members new to the plan who are currently using Tagrisso, except when the product is obtained as samples or via manufacturer's patient assistance programs.
**OR**
Authorization will be granted when all the following criteria has been met, and documentation has been submitted:

1. The member is diagnosed with advanced or metastatic non-small cell lung cancer (NSCLC)
2. The prescriber is an oncologist
3. Appropriate dosing
4. ONE of the following:
    a. The cancer displays EGFR exon 19 deletions or exon 21 L858R mutations
    b. The cancer displays the EGFR mutation and the T790M resistance mutation
    c. The member has had an inadequate response or adverse reaction to one or contraindication to all the following agents:
        - Erlotinib
        - Gilotrif (afatinib)
        - Iressa (gefitinib)
        - Vizimpro (dacomitinib)

**<u>Adjuvant Treatment for Stage IB to IIIA NSCLC</u>**
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Provider attestation or medical records that shows cancer displays the EGFR exon 19 deletions or exon 21 L858R mutation
5. Member has completely resected disease
6. Medical charts showing inadequate response or adverse reaction to at least one platinum-based chemotherapy regimen OR contraindication to the use of platinum-based chemotherapy
7. Quantity requested is ≤1 unit/day

**Continuation of Therapy**

Reauthorization requires physician documentation of continuation of therapy, positive response to therapy when there is no evidence of unacceptable toxicity or disease recurrence while on the current regimen.

**Limitations**

1. Initial approvals and reauthorizations will be granted for
    a. Adjuvant treatment of NSCLC: 12 months (for a maximum of 3 years)
    b. Recurrent, advanced, or metastatic NSCLC: 12 months
2. The following quantity limits apply:

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| Tagrisso | 30 Tablets per 30 days |

- Requests for over the quantity limit should be reviewed against the Global Quantity Limit criteria.

**References**


1. Tagrisso (osimertinib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; August 2018
2. Remon J, Caramella C, Jovelet C, et al. Osimertinib benefit in EGFR-mutant NSCLC patients with T790M-mutation detected by circulating tumour DNA [published online January 18, 2017]. *Ann Oncol.* 2017. pii: mdx017. doi: 10.1093/annonc/mdx017
3. 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;376(7):629-640
4. Jänne PA, Yang JC, Kim DW, et al. AZD9291 in EGFR inhibitor-resistant non-small-cell lung cancer. *N Engl J Med*. 2015;372(18):1689-1699


**Review History**

09/18/19 – Reviewed
10/2/20 – Updated criteria to be in line with Masshealth partial unified formulary requirements: Added appropriate dosing, and Vizimpro for criteria “c”.
11/17/2021 – Updated and reviewed Nov P&T; Added Adjuvant treatment for Stage IB to IIIA NSCLC.
03/16/2022 – Reviewed and Updated for March P&T; Administrative update to continuation of therapy criteria; updated duration of approval for adjuvant treatment of NSCLC to 12 months (up to 3 years) Effective 05/01/2022.