

**Tagrisso (osimertinib)**  
Effective 01/01/2022

<b>Plan</b>	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	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 EGFR 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 AllWays Health Partners 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:

**Advanced or metastatic NSCLC**

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. BOTH of the following:
    - i. The cancer displays the EGFR mutation and the T790M resistance mutation

- ii. 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)
- 5. Quantity requested is  $\leq 1$  unit/day

**Adjuvant Treatment for Stage IB to IIIA NSCLC**

Prescriber provides documentation of ALL of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Documentation or medical records showing that cancer displays the EGFR exon 19 deletions or exon 21 L858R mutation
5. Member has completely resected disease
6. Provider documentation of 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  $\leq 1$  unit/day

**Limitations**

1. Approvals will be granted for 12 months
2. The following quantity limits apply:

Tagrisso	30 Tablets per 30 days
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- 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”.

11/1/2021 – Updated and Reviewed at Nov P&T; Updated to reflect changes to Tagrisso (osimertinib) criteria based on NCCN guidelines for NSCLC (V5.2021). Effective 1/1/2022

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