Tagrisso (osimertinib)
Effective 05/01/2022

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	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
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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 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:

<u>Advanced or metastatic NSCLC</u>

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 ≤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 ≤1 unit/day

Continuation of Therapy

Reauthorization require physician attestation that indicates a positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months
2. The following quantity limits apply:

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".

11/1/2021 – 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
03/16/2022 – Updated and Reviewed at March P&T; Added continuation of therapy criteria. Effective 05/01/2022

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