Clinical Policy: Osimertinib (Tagrisso)

Reference Number: PA.CP.PHAR.294
Effective Date: 01/18
Last Review Date: 04/19 Revision Log

Description
Osimertinib (Tagrisso®) is a tyrosine kinase inhibitor.

FDA Approved Indication(s)
Tagrisso is indicated:

- For the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test
- For the treatment of patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Tagrisso is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all):

1. Diagnosis of recurrent, advanced or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is positive for either of the following (a or b):
   a. Sensitizing EGFR mutation (e.g., exon 19 deletion or insertion; exon 21 point mutation - L858R, L861Q; exon 18 point mutation - G719X; exon 20 point mutation - S768I);
   b. T790M mutation with progression on or after an EGFR TKI therapy (e.g., Tarceva®, Gilotrif®, Iressa®, Vizimpro®);

   **Prior authorization may be required for EGFR TKI therapies.*
5. Dose does not exceed one of the following (a b, or c):
   a. 80 mg (1 tablet) per day;
   b. 160 mg (2 tablets) per day if coadministered with a strong CYP3A4 inducer (e.g., phenytoin, rifampin, carbamazepine, St. John's wort).
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Non-Small Cell Lung Cancer (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies, or documentation supports that member is currently receiving Tagrisso for NSCLC;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
    a. 80 mg (1 tablet) per day;
    b. 160 mg (2 tablets) per day if coadministered with a strong CYP3A4 inducer (e.g., phenytoin, rifampin, carbamazepine, St. John's wort).
    c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
NSCLC: non-small cell lung cancer
TKI: tyrosine kinase inhibitor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Gilotrif (afatinib)	Metastatic NSCLC 40 mg PO QD	40 mg/day 50 mg/day when on chronic concomitant therapy with a P-gp inducer
Iressa (gefitinib)	Metastatic NSCLC 250 mg PO QD	250 mg/day 500 mg/day when used with a strong CYP3A4 inducer
Tarceva (erlotinib)	Metastatic NSCLC 150 mg PO QD	150 mg/day 450 mg/day when used with a strong CYP3A4 inducer or 300 mg/day when used with a moderate CYP1A2 inducer
Vizimpro (dacomitinib)	Metastatic NSCLC 45 mg PO QD	45 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	80 mg PO QD	80 mg/day 160 mg/day when used with a strong CYP3A4 inducer

V. Product Availability

Tablets: 40 mg, 80 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Criteria added for new FDA indication: first-line therapy in EGFR sensitizing exon 19 or exon 21 L858R-mutated, metastatic NSCLC; added prescriber specialty requirement, removed requirement that mutation must be detected by an FDA approved test, references reviewed and updated.	05.18	
2Q 2019 annual review: NCCN designation of advanced added to NSCLC; sensitizing EGFR mutations restated as examples; Vizimpro added as a trial option for prior NSCLC therapy per NCCN; references reviewed and updated.	04.19	

References

1. Tagrisso Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; August 2018. Available at: https://www.tagrisso.com/. Accessed February 1, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 1, 2019.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer. Version 3.2019. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 1, 2019.