Clinical Policy: Osimertinib (Tagrisso)

Reference Number: ERX.SPA.251
Effective Date: 05.29.18
Last Review Date: 11.18 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Osimertinib (Tagrisso®) is a 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
- 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
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is recurrent or metastatic;
5. Disease is positive for any of the following (a, b, or c):
   a. Exon 19 deletions;
   b. Exon 21 L858R mutations;
   c. T790M mutation with progression on or after an EGFR TKI therapy (e.g., Tarceva®, Gilotrif®, or Iressa®);
   **Prior authorization may be required for EGFR TKI therapies*
6. Dose does not exceed one of the following (a or b):
   a. 80 mg per day (1 tablet per day);
   b. 160 mg per day (2 tablets per day) if co-administered with a strong CYP3A4 inducer (e.g., phenytoin, rifampin, carbamazepine, St. John's wort).

Approval duration: Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Tagrisso for NSCLC and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a or b):

a. 80 mg per day (1 tablet per day);
b. 160 mg per day (2 tablets per day) if co-administered with a strong CYP3A4 inducer (e.g., phenytoin, rifampin, carbamazepine, St. John's wort).

Approval duration: Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
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 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 per day when on chronic concomitant therapy with a P-gp inducer
Iressa® (gefitinib)	Metastatic NSCLC 250 mg PO QD	250 mg/day; 500 mg per day when used with a strong CYP3A4 inducer
Tarceva® (erlotinib)	Metastatic NSCLC 150 mg PO QD	150 mg/day; 450 mg per day when used with a strong CYP3A4 inducer or 300 mg per day when used with a moderate CYP1A2 inducer

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.

V. Dosage and Administration

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

VI. Product Availability

Tablets: 80 mg, 40 mg

VII. References

1. Tagrisso Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2017. Available at: https://www.tagrisso.com/. Accessed July 2018.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 2018.

3. National Comprehensive Cancer Network. Non-small cell lung cancer. Version 5.2018. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed July 2018.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.29.18	08.18
4Q 2018 annual review: no significant changes; references reviewed and updated.	08.03.18	11.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.