Clinical Policy: Osimertinib (Tagrisso)

Reference Number: ERX.SPA.251
Effective Date: 09.01.18
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

Revision Log

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

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

FDA Approved Indication(s)
Tagrisso is indicated for the:

- As adjuvant therapy after tumor resection in adult patients with 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
- First-line treatment of patients with metastatic NSCLC whose tumors have 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

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. Request is for one of the following (a or b):
   a. Completely resected stage IB–IIIA EGFR mutation-positive NSCLC who received previous adjuvant chemotherapy or are ineligible to receive platinum-based chemotherapy;
   b. Recurrent, advanced or metastatic NSCLC, and disease is positive for either of the following (i or ii):
      i. 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);
      ii. 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. Prescribed as a single agent;
6. Request meets one of the following (a, b, or c):*
   a. Dose does not exceed 80 mg (1 tablet) per day;
   b. Dose does not exceed 160 mg (2 tablets) per day if co-administered 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 6 months
Commercial – 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, request meets one of the following (a, b, or c):*
   a. New dose does not exceed 80 mg per day (1 tablet per day);
   b. New dose does not exceed 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);
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 12 months
Commercial – 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/day when on chronic concomitant therapy with a P-gp inducer

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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

V. 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

VI. Product Availability
Tablets: 40 mg, 80 mg

VII. References
1. Tagrisso Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2022. Available at: https://www.tagrisso.com/. Accessed February 9, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 9, 2022.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer. Version 2.2022. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 9, 2022.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc. Updated periodically. Accessed February 9, 2022.

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
2Q 2019 annual review: no significant changes; 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.	02.19.19	05.19
2Q 2020 annual review: no significant changes; added Medicaid line of business with 6/12 month initial/continued authorization duration; references reviewed and updated.	02.12.20	05.20
2Q 2021 annual review: RT4: added new indication for use in the adjuvant setting; references reviewed and updated.	01.07.21	05.21
2Q 2022 annual review: added criterion for use as single-agent therapy for NSCLC per NCCN; references reviewed and updated.	02.09.22	05.22

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.