# Clinical Policy: Osimertinib (Tagrisso)

Reference Number: CP.CPA.160
Effective Date: 11.16.16
Last Review Date: 11.17
Line of Business: Medicaid – Medi-Cal

Revision Log

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

## Description

Osmimertinib (Tagrisso®) is a kinase inhibitor for oral use.

## FDA approved indication

Tagrisso is indicated:

- For the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation positive non-small cell lung cancer (NSCLC), as detected by an FDA approved test, who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy
- This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

## Policy/Criteria

*Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria*

It is the policy of health plans affiliated with Centene Corporation® 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. Patient has an EGFR T790M mutation as detected by an FDA-approved test;
3. Failure of Gilotrif, Tarceva or Iressa unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 80 mg/day.

**Approval duration: Length of Benefit**

**B. Other diagnoses/indications**

1. Refer to CP.PHAR.57 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 Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Dose does not exceed 80 mg/day.

**Approval duration: Length of Benefit**

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to CP.PHAR.57 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 – CP.PHAR.57 or evidence of coverage documents

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
EGFR: Epidermal growth factor receptor
NSCLC: Non-small cell lung cancer
TKI: tyrosine kinase inhibitor

*Appendix B: General Information*

- The National Comprehensive Cancer Network recommendation is 2A for: 1. subsequent therapy as a single agent for EGFR T790M mutation-positive metastatic disease following progression on erlotinib, afatinib, or gefitinib for asymptomatic disease or symptomatic systemic lesions 2. for progression on tyrosine kinase inhibitor therapy
- Use in patients with metastatic EGFR T790M mutation positive NSCLC was approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials

*Appendix C: Therapeutic Alternatives*

| Drug | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Gilotrif (afatinib) | ***NSCLC – EGFR mutation:***<br>40 mg PO QD | 40 mg/day |
| Tarceva (erlotinib) | ***NSCLC – EGFR mutation:***<br>150 mg PO QD | 150 mg/day |
| Iressa (gefitinib) | ***NSCLC – EGFR mutation:***<br>250 mg PO QD | 250 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.*

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| NSCLC | 40 mg to 80 mg PO QD | |

## VI. Product Availability

Tablet: 40 mg, 80 mg

## VII. References

1. Tagrisso Prescribing Information. Wilmington, DE. AstraZeneca Pharmaceuticals LP, September 2016. Available at www.tagrisso.com Accessed January 2017.
2. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 4.2016. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed January 2017.
3. Tagrisso Drug Monograph. Clinical Pharmacology. Accessed January 2017. http://www.clinicalpharmacology-ip.com
4. Tagrisso. American Hospital Formulary Service Drug Information. Available at: http://www.medicinescomplete.com/mc/ahfs/current/. Accessed January 2017.
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 2017.
6. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 2017.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Converted to new template. Minor changes to verbiage and grammar. References updated. | 01.11.17 | 11.17 |

**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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.