

Clinical Policy: Erlotinib (Tarceva)

Reference Number: CP.PHAR.74

Effective Date: 09.01.11

Last Review Date: 05.20

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Erlotinib (Tarceva[®]) is a kinase inhibitor.

FDA Approved Indication(s)

Tarceva is indicated for the 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) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen.
- Locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine as first-line.

Limitation(s) of use:

- Safety and efficacy of Tarceva have not been established in patients with NSCLC whose tumors have other EGFR mutations.
- Tarceva is not recommended for use in combination with platinum based chemotherapy.

Policy/Criteria

Provider must submit documentation (including 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 Centene Corporation[®] that Tarceva 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 \geq 18 years;
4. Disease is positive for 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);
5. Tarceva may be prescribed as a single agent, in combination with Cyramza[®], or in combination with bevacizumab;
6. For use in combination with bevacizumab: disease histology is nonsquamous NSCLC;
7. Request meets one of the following (a or b):*

- a. Dose does not exceed 450 mg (4 tablets) per day;
- b. 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/HIM – 6 months

Commercial – Length of Benefit

B. Pancreatic Cancer (must meet all):

1. Diagnosis of locally advanced, unresectable or metastatic pancreatic cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Prescribed in combination with gemcitabine;
5. Request meets one of the following (a or b):*
 - a. Dose does not exceed 450 mg (4 tablets) per day;
 - b. 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/HIM – 6 months

Commercial – Length of Benefit

C. Bone Cancer (off-label) (must meet all):

1. Diagnosis of recurrent chordoma;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Dose is within FDA maximum limit for any FDA-approved indication or 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/HIM – 6 months

Commercial – Length of Benefit

D. Renal Cell Carcinoma (off-label) (must meet all):

1. Diagnosis of relapsed or stage IV (unresectable or metastatic) renal cell carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Histology is non-clear cell;
5. Dose is within FDA maximum limit for any FDA-approved indication or 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/HIM – 6 months

Commercial – Length of Benefit

E. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Tarceva for a covered indication 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 or b):*
 - a. New dose does not exceed 450 mg (4 tablets) per day;
 - b. 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/HIM – 12 months

Commercial – 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 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

EGFR: epidermal growth factor receptor

NSCLC: non-small cell lung cancer

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	150 mg PO QD Up to 300 mg/day with concurrent tobacco smoking Up to 450 mg/day if taken with a CYP3A4 inducer	450 mg/day
Pancreatic cancer	100 mg PO QD Up to 300 mg/day with concurrent tobacco smoking Up to 450 mg/day if taken with a CYP3A4 inducer	450 mg/day

VI. Product Availability

Tablets: 25 mg, 100 mg, 150 mg

VII. References

1. Tarceva Prescribing Information. Northbrook, IL: OSI Pharmaceuticals LLC; October 2016. Available at http://www.gene.com/download/pdf/tarceva_prescribing.pdf. Accessed June 26, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed June 26, 2020.
3. National Comprehensive Cancer Network. Non-small Cell Lung Cancer Version 6.2020. Available at nccn.org. Accessed June 26, 2020.
4. National Comprehensive Cancer Network. Central Nervous System Cancers Version 3.2019. Available at nccn.org. Accessed February 11, 2020.
5. National Comprehensive Cancer Network. Pancreatic Adenocarcinoma Version 1.2020. Available at nccn.org. Accessed February 11, 2020.
6. National Comprehensive Cancer Network. Bone Cancer Version 1.2020. Available at nccn.org. Accessed February 11, 2020.
7. National Comprehensive Cancer Network. Kidney Cancer Version 2.2020. Available at nccn.org. Accessed February 11, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added Tarceva mechanism of action and bioavailability to background. Edited Appendix B: Dosing Combined Appendix E with D Added age limitation to adults per package insert. Added reference to Appendix C wherever asks about toxicity. Replaced monotherapy restriction in the NSCLC questions with the more specific platinum-based therapy restriction per the PI limitations of use section – reflected this edit in the policy’s indications section as well. Supplemented question about performance status (PS) for pancreatic cancer with NCCN guideline language in Appendix D. Supplemented	6.15	08.15

Reviews, Revisions, and Approvals	Date	P&T Approval Date
question about PS for NSCLC with NCCN guideline language in Appendix D and added a question under PS 3-4 in the algorithm about EGFR sensitive mutations per NCCN guidelines.		
Policy converted to new template. NSCLC: FDA approved use criteria is made slightly less specific to incorporate NCCN compendial uses that are similar but less restrictive. Added one additional “off-label” NSCLC use under Section I.A.2.b. “NCCN recommended use”. Pancreatic cancer: FDA and NCCN indications presented as one criteria set. Additional NCCN uses: all additional NCCN recommended uses are listed under Section C – “other diagnoses/indications”.	06.16	08.16
Language for NSCLC maintenance therapy changed to “maintenance therapy for metastatic disease after prior chemotherapy”. Maintenance therapy is deleted from the NSCLC NCCN recommended use. Vulvar cancer is added as an additional recommended use. Under section II. Continued Approval, the following edits are made to reasons to discontinue: 1) Added “If pre-existing hepatic impairment or biliary obstruction, a doubling of bilirubin or tripling of transaminase (ALT/AST) values over baseline that does not improve significantly or resolve within 3 weeks”; 2) removed “no disease progression or unacceptable toxicities.”	11.16	12.16
Updated approval duration to 6 and 12 months; Added NCCN compendium use for pancreatic cancer; Added max dose; Added criteria for off-label uses of Bone cancer – chordoma; Central nervous system cancers-Brain Metastases; and Kidney cancer per NCCN guidelines and compendium. Removed criteria for vulvar cancer since it is a 2b category and only 1 and 2b categories are addressed in the policy. Removed reasons to discontinue per new safety strategy.	08.22.17	11.17
1Q18 annual review: - Policies combined for Centene Medicaid, Marketplace and Commercial lines of business - Added age to FDA approved indications - For Medicaid NSCLC/ Pancreatic Cancer: replaces specific disease conditions with general language to ensure coverage of both NCCN recommended uses and FDA approved uses - References reviewed and updated	11.14.17	02.18
2Q 2019 annual review: NCCN designation of advanced added to NSCLC; CNS metastasis moved from off-label section and incorporated into NSCLC criteria set; age added to off-label indications; trial requirement removed from RCC since non-clear cell histology; continuation of care added; references reviewed and updated.	02.19.19	05.19

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2020 annual review: added quantity limits of 4 tablets per day; references reviewed and updated.	02.11.20	05.20
RT4: added NCCN-supported combination of Tarceva with either Cyramza or bevacizumab; references reviewed and updated.	06.26.20	

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.

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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.

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