Clinical Policy: Erlotinib (Tarceva)

Reference Number: PA.CP.PHAR.74
Effective Date: 01/18
Last Review Date: 04/19 Revision Log

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.
- Patients with 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
It is the policy of Pennsylvania Health and Wellness 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 ≥ 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. Request meets one of the following (a or b):
   a. Dose does not exceed 450 mg per day;
   b. 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. 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 ≥ 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 per day;
b. 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

C. Bone Cancer (off-label) (must meet all)**:**
1. Diagnosis of recurrent chordoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 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).

Approval duration: 6 months

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 ≥ 18 years;
4. Histology is non-clear cell;
   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)*.

Approval duration: 6 months

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

II. Continued Approval

A. All Indications (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;
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 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*).

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

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

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
Gemcitabine	Varies	Varies

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	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

V. Product Availability

Tablets: 25 mg, 100 mg, 150 mg

VI. References

1. Tarceva Prescribing Information. Northbrook, IL: OSI Pharmaceuticals LLC; October 2016. Available at http://www.gene.com/download/pdf/tarceva_prescribing.pdf. Accessed January 31, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed January 31, 2019.
3. National Comprehensive Cancer Network. Non-small Cell Lung Cancer Version 3.2019. Available at nccn.org. Accessed January 31, 2019.
4. National Comprehensive Cancer Network. Central Nervous System Cancers Version 2.2018. Available at nccn.org. Accessed January 31, 2019.
5. National Comprehensive Cancer Network. Pancreatic Adenocarcinoma Version 1.2019. Available at nccn.org. Accessed January 31, 2019.
6. National Comprehensive Cancer Network. Bone Cancer Version 1.2019. Available at nccn.org. Accessed January 31, 2019.
7. National Comprehensive Cancer Network. Kidney Cancer Version 2.2019. Available at nccn.org. Accessed January 31, 2019.

VII.

Reviews, Revisions, and Approvals	Date	Approval Date
Added age to FDA approved indications. For NSCLC/ Pancreatic Cancer: replaces specific disease conditions with general language to ensure coverage of both NCCN recommended uses and FDA approved uses. 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. References reviewed and updated	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.	04/19	