PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Erlotinib Prior Authorization Policy
- Tarceva® (erlotinib tablets – Genentech, generic)

REVIEW DATE: 02/26/2025

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Erlotinib, a tyrosine kinase inhibitor, is indicated for the following uses:[1]

- **Non-Small Cell Lung Cancer (NSCLC)**, treatment of patients 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. Limitations of use: The safety and efficacy of erlotinib have not been established in patients with NSCLC whose tumors have other *EGFR* mutations. Erlotinib is not recommended for use in combination with platinum-based chemotherapy.
- **Pancreatic Cancer**, in combination with gemcitabine as first-line treatment of patients with locally advanced, unresectable, or metastatic pancreatic cancer.

Guidelines

Erlotinib is addressed in the National Comprehensive Cancer Network (NCCN) guidelines.[2-7]

- **Bone Cancer:** Guidelines (version 1.2025 – August 20, 2024) note erlotinib (category 2A) as a treatment option under "Useful in Certain Circumstances" for patients with chordoma.[3] The efficacy of erlotinib was demonstrated in patients with advanced chordoma resistant to imatinib.
- **Kidney Cancer:** Guidelines (version 3.2025 – January 9, 2025) no longer recommend erlotinib monotherapy as a treatment option for patients with recurrent or advanced renal cell carcinoma (RCC) of non-clear cell histology .[6] The combination of bevacizumab with erlotinib is a treatment option (category 2A) for non-clear cell histology RCC in selected patients with advanced papillary RCC, including hereditary leiomyomatosis and renal cell cancer (HLRCC)-associated RCC under "Other Recommended Regimens".
- **Non-Small Cell Lung Cancer:** Guidelines (version 3.2025 – January 14, 2025) recommend erlotinib and other *EGFR* tyrosine kinase inhibitors as first-line treatment for patients with advanced or metastatic NSCLC with *EGFR* exon 19 deletions, exon 21 (L858R) substitution mutations (category 1 for both exon 19 and exon 21), L861Q, G719X, and S768I (category 2A for these three mutations).[4] Erlotinib can be used in combination with bevacizumab or ramucirumab in this setting (category 2A both combinations).
- **Pancreatic Adenocarcinoma:** Guidelines (version 2.2025 – February 3, 2025) recommend the combination of gemcitabine and erlotinib as first-line treatment option (category 1) for patients with metastatic disease under "Other Recommended Regimens".[5] The combination is also recommended for locally advanced first-line therapy (category 2A). In addition, the combination is recommended as a subsequent therapy option (category 2A) for locally advanced, metastatic, or recurrent disease under "Other Recommended Regimens".
- **Vulvar Cancer:** Guidelines (version 1.2025 – February 10, 2025) recommend erlotinib (category 2B) as a second-line or subsequent treatment option for patients with advanced, recurrent, or metastatic vulvar cancer under "Other Recommended Regimens".[7]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of erlotinib. All approvals are provided for the duration noted below.

- **Tarceva® (erlotinib tablets - Genentech, generic)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND
B) Patient has advanced or metastatic disease; AND
C) Patient has *EGFR* mutation-positive non-small cell lung cancer as detected by an approved test.
Note: Examples of *EGFR* mutation-positive non-small cell lung cancer include the following: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X, and S768I.

2. **Pancreatic Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has locally advanced, metastatic, or recurrent disease; AND
   C) The medication is used in combination with gemcitabine.

Other Uses with Supportive Evidence

3. **Bone Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has chordoma; AND
   C) Patient has tried at least one previous therapy.

4. **Renal Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has Stage IV or relapsed renal cell carcinoma of non-clear cell histology; AND
   C) Patient meets BOTH of the following (i and ii):
      i. Patient has advanced papillary disease including hereditary leiomyomatosis and renal cell carcinoma (HLRCC)-associated renal cell carcinoma; AND
      ii. The medication is used in combination with bevacizumab.

5. **Vulvar Cancer.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has advanced, recurrent, or metastatic disease.

CONDITIONS NOT COVERED

- **Tarceva® (erlotinib tablets - Genentech, generic)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Renal Cell Carcinoma, Advanced – Clear Cell Histology.** NCCN Kidney Cancer guidelines (version 3.2025 – January 9, 2025) do not note erlotinib as a treatment option for advanced clear-cell renal cell carcinoma.[6]

REFERENCES

1. Tarceva® tablets [prescribing information]. South San Francisco, CA: Genentech; October 2016.
2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 24, 2025. Search terms: erlotinib.
3. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – August 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 10, 2025.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – January 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 24, 2025.
5. The NCCN Pancreatic Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2025 – February 3, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 24, 2025.
6. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – January 9, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 24, 2025.
7. The NCCN Vulvar Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – February 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 24, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/25/2023
Annual Revision	**Non-Small Cell Lung cancer:** Deleted the word "sensitizing" while referring to *EGFR* mutations both in criteria and in the Note. Guidelines no longer use the word sensitizing to describe *EGFR* mutations.	02/07/2024
Annual Revision	**Renal Cell Carcinoma:** Changed disease qualifier description from "recurrent or advanced" to "Stage IV or relapsed" disease. Previously, for non-clear cell histology, erlotinib could be used as monotherapy for non-clear cell histology or in combination with bevacizumab for hereditary leiomyomatosis and renal cell carcinoma (HLRCC). Now, erlotinib monotherapy is no longer recommended in guidelines. So the "OR" separating the criteria describing Stage IV or relapsed disease and HLRCC was changed to an "AND". In addition, for criterion referring to HLRCC, added "advanced papillary disease including HLRCC-associated renal cell carcinoma." **Breast Cancer:** Deleted condition listed under "Conditions Not Covered ". **Colon Cancer, Advanced**: Deleted condition listed under "Conditions Not Covered ". **Glioblastoma Multiforme (GBM)**: Deleted condition listed under "Conditions Not Covered ". **Head and Neck Cancer**: Deleted condition listed under "Conditions Not Covered ".	02/26/2025

	Hepatocellular Carcinoma, Advanced: Deleted condition listed under "Conditions Not Covered ".	