Reference number(s)
1664-A

SPECIALTY GUIDELINE MANAGEMENT

erlotinib

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Non-Small Cell Lung Cancer (NSCLC)
   Erlotinib 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.

   Limitations of use:
   a. Safety and efficacy of erlotinib have not been established in patients with NSCLC whose tumors have other EGFR mutations.
   b. Erlotinib is not recommended for use in combination with platinum-based chemotherapy.

2. Pancreatic cancer
   Erlotinib in combination with gemcitabine is indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.

B. Compendial Uses

1. NSCLC, recurrent, advanced or metastatic sensitizing EGFR mutation-positive
2. Recurrent bone cancer – recurrent chordoma
3. Renal cell carcinoma, relapsed or stage IV disease with non-clear cell histology
4. Brain metastases from EGFR sensitizing mutation-positive NSCLC
5. Recurrent pancreatic cancer

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: EGFR mutation testing results (where applicable).

III. CRITERIA FOR INITIAL APPROVAL

A. Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for treatment of recurrent, advanced or metastatic NSCLC (including brain metastases from NSCLC) when the member has sensitizing EGFR mutation-positive disease as a single agent or in combination with ramucirumab or bevacizumab.

B. Pancreatic cancer
Authorization of 12 months may be granted for treatment of locally advanced, unresectable, recurrent or metastatic pancreatic cancer in combination with gemcitabine.

C. Renal cell carcinoma (RCC)
Authorization of 12 months may be granted for treatment of relapsed or stage IV renal cell carcinoma with non-clear cell histology as a single agent or in combination with bevacizumab.

D. Chordoma
Authorization of 12 months may be granted for treatment of recurrent chordoma as a single agent.

IV. CONTINUATION OF THERAPY

A. Non-small cell lung cancer (NSCLC)
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for EGFR positive NSCLC when either of the following criteria are met:
1. There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
2. Disease is T790M negative and there is no evidence of unacceptable toxicity.

B. All other indications
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for all other indications listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Erlotinib [package insert]. Pennington, NJ: Zydus Pharmaceuticals USA, Inc.; October 2023.
2. The NCCN Drugs & Biologics Compendium © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 4, 2024.