Reference number(s)
1664-A

SPECIALTY GUIDELINE MANAGEMENT

TARCEVA (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)
      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.

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

   2. Pancreatic cancer
      Tarceva 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
   2. Bone cancer – chordoma
   3. Renal cell carcinoma
   4. Brain metastases from EGFR sensitizing mutation-positive NSCLC

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Non-small cell lung cancer (NSCLC)
Authorization of 12 months may be granted for treatment of NSCLC when the member has a known sensitizing EGFR mutation (including brain metastases from NSCLC).

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

C. Renal cell carcinoma (RCC)
Authorization of 12 months may be granted for treatment of RCC.

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D. Chordoma
Authorization of 12 months may be granted for treatment of chordoma.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Tarceva [package insert]. South San Francisco, CA: Genentech USA, Inc.; October 2016.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 22, 2018.
3. The NCCN Clinical Practice Guidelines in Oncology®: Non-Small Cell Lung Cancer (Version 3.2018). © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 20, 2018.
4. The NCCN Clinical Practice Guidelines in Oncology® Pancreatic Adenocarcinoma (Version 3.2017). © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 27, 2018.
5. The NCCN Clinical Practice Guidelines in Oncology®: Bone Cancer (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 27, 2018.
6. The NCCN Clinical Practice Guidelines in Oncology®: Kidney Cancer (Version 3.2018). © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 27, 2018.
7. The NCCN Clinical Practice Guidelines in Oncology®: Central Nervous System Cancers (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 22, 2018.

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