SPECIALTY GUIDELINE MANAGEMENT

TABRECTA (capmatinib)

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.

FDA-Approved Indications

A. Tabrecta is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

Compendial Use

B. Treatment of recurrent or advanced non-small cell lung cancer in patients with MET exon 14 skipping positive tumors.

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: Documentation of a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping in tumor specimens.

III. CRITERIA FOR INITIAL APPROVAL

Non-small Cell Lung Cancer

Authorization of 12 months may be granted for treatment as a single agent for recurrent, advanced, or metastatic NSCLC with MET exon 14 skipping positive tumors.

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

- 1. Tabrecta [package insert]. East Hanover, NJ: Novartis Pharmaceutical Corporation; May 2020.
- 2. The NCCN Drugs & Biologics Compendium 2021 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed July 6, 2021.

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