

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Tabrecta Prior Authorization Policy

- Tabrecta[®] (capmatinib tablets – Novartis)

REVIEW DATE: 01/26/2022

OVERVIEW

Tabrecta, a kinase inhibitor, is indicated for the treatment of adults 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.¹ This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Guidelines

The National Comprehensive Cancer Network (NCCN) NSCLC guidelines (version 1.2022 – December 7, 2021) recommend testing for *MET* exon 14 skipping mutations in eligible patients with metastatic disease. NCCN recommends Tabrecta as a first-line therapy for patients with metastatic NSCLC who are positive for *MET* exon 14 skipping mutations or high-level *MET* amplification. Tabrecta is also recommended as a subsequent treatment option in patients with *MET* exon 14 skipping mutation-positive metastatic NSCLC who were not previously treated with Tabrecta, Tepmetko[®] (tepotinib tablets), or Xalkori[®] (crizotinib capsules).

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tabrecta is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer.** Approve for 3 years if the patient meets the following criteria (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has metastatic disease; AND
 - C) Patient meets one of the following criteria (i or ii):
 - i. Patient has mesenchymal epithelial transition (*MET*) exon 14 skipping mutations as detected by an approved test; OR
 - ii. Patient has high-level *MET* amplification as detected by an approved test.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tabrecta is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tabrecta® tablets [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2020.
 2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2022 – December 7, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org/>. Accessed on January 21, 2022.
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