

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Tepmetko Prior Authorization Policy

- Tepmetko® (tepotinib tablets – EMD Serono)

REVIEW DATE: 02/08/2021

OVERVIEW

Tepmetko, a kinase inhibitor, is indicated for the treatment of adult patients with **metastatic non-small cell lung cancer (NSCLC)** harboring mesenchymal-epithelial transition (**MET**) **exon 14 skipping alterations**.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 trials.

Guidelines

Tepmetko is not addressed in the guidelines. The National Comprehensive Cancer Network (NCCN) non-small cell lung cancer guidelines (version 2.2021 – December 15, 2020) recommend Tabrecta™ (capmatinib tablets) as the “preferred” first-line therapy (category 2A) in patients with **MET** exon 14 skipping mutation discovered prior to first-line systemic therapy. Xalkori® (crizotinib capsules) is recommended (category 2A) as “useful in certain circumstances” in this setting. In patients with **MET** exon 14 skipping mutation discovered during first-line systemic therapy, Tabrecta or Xalkori are recommended (both category 2A) after completion of planned systemic therapy or systemic therapy can be interrupted followed by either one of these targeted therapies.

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Non-Small Cell Lung Cancer (NSCLC).** 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) The tumor is positive for mesenchymal-epithelial transition (**MET**) exon 14 skipping alterations.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tepmetko 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. Tepmetko® tablets [prescribing information]. Rockland, MA: EMD Serono, Inc.; February 2021.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 2.2021 – December 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on February 3, 2021.