PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Tepmetko Prior Authorization Policy

• Tepmetko[®] (tepotinib tablets – EMD Serono)

REVIEW DATE: 02/07/2024

OVERVIEW

Tepmetko, a kinase inhibitor, is indicated for the treatment of metastatic **non-small cell lung cancer** (**NSCLC**) in adults 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

The National Comprehensive Cancer Network (NCCN) NSCLC guidelines (version 1.2024 – December 21, 2023) recommend Tepmetko (category 2A) as a "Preferred" first-line or subsequent line treatment option for patients with advanced or metastatic NSCLC who are positive for *MET* exon 14 skipping mutations or high-level *MET* amplification.²

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 Indication

- 1. Non-Small Cell Lung Cancer. Approve for 1 year if the patient meets the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - **B)** Patient has advanced or metastatic disease; AND
 - C) Patient meets one of the following (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.

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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; March 2023.
- 2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2024 December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on February 6, 2024.