



PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Tepmetko Prior Authorization Policy

- Tepmetko® (tepotinib tablets – EMD Serono)

REVIEW DATE: 02/07/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

- **Tepmetko® (tepotinib tablets (EMD Serono)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 \geq 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.

CONDITIONS NOT COVERED

- **Tepmetko® (tepotinib tablets (EMD Serono)**

is(are) considered experimental, investigational or unproven for ANY other use(s).

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Non-Small Cell Lung Cancer: Criterion that patient has metastatic disease was changed to include advanced; revised to read: Patient has advanced or metastatic disease.	02/01/2023
Annual Revision	No criteria changes.	02/07/2024

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