Clinical Policy: Tepotinib (Tepmetko)

Reference Number: ERX.SPA.432
Effective Date: 06.01.21
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Tepotinib (Tepmetko®) is a kinase inhibitor that targets mesenchymal-epithelial transition (*MET*).

FDA Approved Indication(s)
Tepmetko is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring *MET* exon 14 skipping alterations.

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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Tepmetko is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of recurrent, advanced, or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is positive for a mutation causing *MET* exon 14 skipping or high-level *MET* amplification;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 450 mg (2 tablets) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 6 months
Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Tepmetko for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;

3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 450 mg (2 tablets) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MET: mesenchymal-epithelial transition
NCCN: National Comprehensive Cancer Network
NSCLC: non-small cell lung cancer

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information
- *MET* amplification is an oncogenic driver occurring in 1% to 5% of NSCLCs that confers a poor prognosis and lacks approved targeted therapies. High-level *MET* amplification is an emerging biomarker to identify novel therapies for patients with metastatic NSCL per NCCN. The definition of high-level *MET* amplification is evolving and may differ according to the assay used for testing. For NGS-based results, a copy number greater than 10 is consistent with high-level *MET* amplification. (NCCN NSCLC Guideline Version 1.2022)

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	450 mg PO QD	450 mg/day

VI. Product Availability

Tablet: 225 mg

VII. References

1. Tepmetko Prescribing Information. Rockland, MA: EMD Serono, Inc.; February 2021. Available at: www.tepmetko.com. Accessed February 13, 2022.
2. NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 13, 2022.
3. Paik PK, Felip E, Veillon R, et al. Tepotinib in Non–Small-Cell Lung Cancer with MET Exon 14 Skipping Mutations. N Engl J Med 2020;383:931-43.

4. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT02864992, Tepotinib Phase II in Non-small Cell Lung Cancer (NSCLC) Harboring MET Alterations (VISION); 2021 January 20. Available at: https://clinicaltrials.gov/ct2/show/NCT02864992?term=NCT02864992&draw=2&rank=1 . Accessed February 11, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	02.11.21	05.21
2Q 2022 annual review: added indication of high-level *MET* amplification in NSCLC per NCCN category 2A; added qualifier for recurrent NSCLC; removed criteria for EGFR wild-type and ALK negative statuses and exclusion for CNS metastases neither NCCN nor the FDA labeling support this restriction; added references reviewed and updated.	02.13.22	05.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.