

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2023 P 1355-3
Program	Prior Authorization/Notification
Medication	Tepmetko® (tepotinib)
P&T Approval Date	4/2021, 4/2022, 4/2023
Effective Date	7/1/2023; Oxford only: 7/1/2023

**1. Background:**

Tepmetko® (tepotinib) is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymalepithelial-transition (MET) exon 14 skipping alterations.<sup>1</sup>

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.

The National Comprehensive Cancer Network (NCCN) recommends use of Tepmetko for recurrent, advanced, or metastatic disease in patients with MET exon 14 skipping mutation positive tumors as first-line therapy and subsequent therapy following progression on first-line systemic therapy with a non-MET exon 14 skipping mutation-targeted regimen.

**Coverage Information:**

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

**2. Coverage Criteria<sup>a</sup>:**

**A. Patients less than 19 years of age**

1. **Tepmetko** will be approved based on the following criterion:

a. Patient is less than 19 years of age

**Authorization will be issued for 12 months.**

**B. Non-Small Cell Lung Cancer**

1. **Initial Authorization**

a. **Tepmetko** will be approved based on **all** of the following criteria:

(1) Diagnosis of non-small cell lung cancer

-AND-

(2) Disease is recurrent, advanced, or metastatic

**-AND-**

(3) Tumor is MET exon 14 skipping mutation positive

**Authorization will be issued for 12 months.**

**2. Reauthorization Criteria**

a. **Tepmetko** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tepmetko therapy

**Authorization will be issued for 12 months.**

**C. NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

**Authorization will be issued for 12 months.**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or Step Therapy may be in place.

**4. References:**

1. Tepmetko [package insert]. Rockland, MA: EMD Serono, Inc.; February 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [https://www.nccn.org/professionals/drug\\_compendium/content/](https://www.nccn.org/professionals/drug_compendium/content/). Accessed February 15, 2023.

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<b>Change Control</b>	
4/2021	New program.
4/2022	Annual review with no change to clinical criteria. Updated reference.
4/2023	Annual review with no change to clinical criteria. Added state mandate footnote. Updated background and references.