

<b>Clinical Policy Title:</b>	tepotinib
<b>Policy Number:</b>	RxA.681
<b>Drug(s) Applied:</b>	Tepmetko®
<b>Original Policy Date:</b>	06/15/2021
<b>Last Review Date:</b>	08/28/2024
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Non-Small Cell Lung Cancer (NSCLC) (must see all):

1. Diagnosis of recurrent, advanced or metastatic NSCLC with MET exon 14 skipping alterations;
2. Prescribed as monotherapy;
3. Disease is positive for a mutation causing MET exon 14 skipping or high-level MET amplification.

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

### II. Continued Therapy Approval

#### A. Non-Small Cell Lung Cancer (must see all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

## References

1. NCCN Guidelines. Non-small Cell Lung Cancer. Version 8.2024. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/nscl.pdf](https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf). Accessed August 28, 2024.
2. Paik PK, Veillon R, Cortot AB, et al. Phase II study of tepotinib in NSCLC patients with METex14 mutations [abstract]. J Clin Oncol 2019; 37: Abstract 9005. Available at: [https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.15\\_suppl.9005](https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.15_suppl.9005). August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established.	04/12/2021	06/10/2021
Policy was reviewed: 1. References were reviewed and updated.	02/01/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of advanced NSCLC with	01/27/2023	04/13/2023

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>MET exon 14 skipping alterations to Diagnosis of recurrent, advanced or metastatic NSCLC with MET exon 14 skipping alterations.</p> <p>2. Initial Approval Criteria, I.A.5: Updated to include new diagnostic criteria Disease is positive for a mutation causing MET exon 14 skipping or high-level MET amplification.</p> <p>3. Reference were reviewed and updated.</p>		
<p>Policy was reviewed.</p>	<p>10/19/2023</p>	<p>10/19/2023</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Removed prescriber restrictions.</li> <li>2. Removed age restrictions.</li> <li>3. Removed dose restrictions.</li> <li>4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.</li> <li>5. Removed reauthorization requirement for positive response to therapy.</li> <li>6. Updated approval duration verbiage.</li> <li>7. References were reviewed and updated.</li> </ol>	<p>08/28/2024</p>	<p>9/13/2024</p>