Pharmacy Policy Bulletin: J-0275 MET Kinase Inhibitors – Commercial and Healthcare Reform	
Number: J-0275	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0275-007	**Original Date:** 08/05/2020
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Tabrecta (capmatinib) • Tepmetko (tepotinib)

FDA-Approved Indication(s):	• Tabrecta (capmatinib)
	  ○ Treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test
	• Tepmetko (tepotinib)
	  ○ Treatment of adult patients with metastatic NSCLC harboring MET exon 14 skipping alterations

Background:	• *MET* exon 14 skipping, a known oncogenic driver, results in reduced negative regulation of oncogenic cells and increased downstream *MET* signaling.
	• The *MET* exon 14 skipping mutation accounts for approximately 3% of NSCLC cases. This mutation is more common in individuals over 70 years of age and a smoking history.
	• Tabrecta and Tepmetko are kinase inhibitors that target *MET*,including the mutant variant produced by exon 14 skipping. They preventthe phosphorylation of *MET* and *MET*-mediated phosphorylation of downstream signaling proteins, which causes a reduction in the proliferation and survival of *MET*-dependent cancer cells.
	• FDA-approved tests for *MET* exon 14 skipping include FoundationOne CDx and FoundationOne Liquid CDx.
	• Prescribing Considerations
	  ○ Tabrecta
	  ▪ Tabrecta carries warnings and precautions for interstitial lung disease (ILD)/pneumonitis, hepatotoxicity, pancreatic toxicity, risk of photosensitivity, and embryo-fetal toxicity.
	  ▪ Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis.

	▪ Liver function tests should be monitored prior to the start of Tabrecta, every 2 weeks during the first 3 months of treatment, and once a month thereafter. ○ Tepmetko ▪ Tepmetko carries warnings and precautions for ILD/pneumonitis, hepatoxicity, and embryo-fetal toxicity. ▪ Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. ▪ Liver function tests should be monitored prior to the start of Tepmetko, every 2 weeks during the first 3 months of treatment, and once a month thereafter or as clinically indicated. ○ *MET* kinase inhibitors should be prescribed by a hematologist/oncologist.

Approval Criteria

I. Initial Authorization

A. Tabrecta (capmatinib)
When a benefit, coverage of Tabrecta may be approved when all of the following criteria are met **(1., 2., and 3.)**:
1. The member is 18 years of age or older.
2. The member has a diagnosis of metastatic NSCLC (ICD-10: C33, C34).
3. The member has a *MET* exon 14 skipping mutation as detected by an FDA approved test.

B. Tepmetko (tepotinib)
When a benefit, coverage of Tepmetko may be approved when all of the following criteria are met **(1., 2., and 3.)**:
1. The member is 18 years of age or older.
2. The member has a diagnosis of metastatic NSCLC (ICD-10: C33, C34).
3. The member has a *MET* exon 14 skipping alteration.

II. Reauthorization
When a benefit, reauthorization of a *MET* kinase inhibitor may be approved when the following criterion is met **(A.)**:
A. The prescriber attests that the member is tolerating therapy and has experienced a therapeutic response defined as one (1) of the following **(1. or 2.)**:
1. Disease improvement
2. Delayed disease progression

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

IV. Coverage of oncology drug(s) listed in this policy may be approved on a case-by-case basis per indications supported in the most current NCCN guidelines.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Tabrecta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2024.
2. Tepmetko [package insert]. Rockland, Massachusetts: EMD Serono, Inc.; February 2024.
3. Fujino T, Suda K, Mitsudomi T. Lung Cancer with MET exon 14 Skipping Mutation: Genetic Feature, Current Treatments, and Future Challenges. *Lung Cancer (Auckl).* 2021 May 20;12:35-50.
4. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2024.
5. NCCN Guidelines Version 1.2024 Non-Small Cell Lung Cancer. National Comprehensive Cancer Network. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 1, 2024.
6. U.S. Food and Drug Administration. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools. Accessed February 1, 2024.