

Tabrecta™ (capmatinib) (Oral)

Document Number: IC-0536

Last Review Date: 05/03/2021

Date of Origin: 6/02/2020

Dates Reviewed: 06/2020, 05/2021

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Tabrecta 150 mg tablets: 4 per day
- Tabrecta 200 mg tablets: 4 per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 800 mg per day

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**

Universal Criteria ¹⁻³

- Must be used as a single agent; **AND**
- Patient will avoid coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, efavirenz, etc.); **AND**
- Therapy will not be used concomitantly with other tyrosine-protein kinase mesenchymal-epithelial transition [cMET] or Hepatocyte Growth Factor Receptor [HGFR]-inhibitors (i.e., crizotinib); **AND**
- Patient has not previously failed treatment with cMET or HGF -inhibitors (e.g., crizotinib, etc.); **AND**

Non-Small Cell Lung Cancer (NSCLC) † ‡ ◊ ¹⁻³

- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**

- Patient’s disease has a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved or CLIA compliant test❖;
OR
- Patient has disease with a high-level of MET-amplification that is amenable to therapy

❖ *If confirmed using an immunotherapy assay* <http://www.fda.gov/companiondiagnostics>

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹

Coverage can be renewed based on the following criteria:

- Patient continues to meet the universal and indication specific criteria as identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: interstitial lung disease (ILD), pneumonitis, severe hepatotoxicity, severe photosensitivity, etc.

V. Dosage/Administration

Indication	Dose
NSCLC	Administer 400 mg orally twice daily with or without food, until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic, nos
- C9399 – Unclassified drugs or biologicals (*for hospital outpatient use ONLY*)

NDC:

- Tabrecta 150 mg tablet: 00078-0709-xx
- Tabrecta 200 mg tablet: 00078-0716-xx

VII. References

1. Tepmetko [package insert]. East Hanover, NJ; Novartis Pharmaceuticals, Inc., May 2020. Accessed April 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) for capmatinib. National Comprehensive Cancer Network, 2021. The NCCN Compendium[®] is a derivative work of the NCCN Guidelines[®]. NATIONAL COMPREHENSIVE CANCER NETWORK[®], NCCN[®], and NCCN GUIDELINES[®] are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most

recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2021.

- ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 4/2/20 . Identifier NCT02414139, Clinical Study of Oral cMET Inhibitor INC280 in Adult Patients With EGFR Wild-type Advanced Non-small Cell Lung Cancer; [Accessed 5/7/20]; [about 4 screens]. Available from:
<https://clinicaltrials.gov/ct2/show/NCT02414139?term=NCT02414139&draw=2&rank=1>.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Article (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC