# Tabrecta® (capmatinib)
## (Oral)

Document Number: IC-0536

**Last Review Date: 05/04/2023**
**Date of Origin:** 6/02/2020
**Dates Reviewed: 06/2020, 05/2021, 05/2022, 05/2023**

## I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

## II. Dosing Limits

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

- Tabrecta 150 mg tablets: 4 tablets per day
- Tabrecta 200 mg tablets: 4 tablets 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 of age; **AND**

### Universal Criteria [1]

- 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, tepotinib, etc.); **AND**
- Patient has not previously failed treatment with cMET or HGF-inhibitors (e.g., crizotinib, tepotinib, etc.); **AND**

### Non-Small Cell Lung Cancer (NSCLC) † ‡ Φ [1-4]

- Patient has mesenchymal-epithelial transition (MET) exon 14 (METex14) skipping mutation positive disease as detected by an FDA-approved or CLIA compliant test❖; **AND**

- 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; **OR**

- Patient has metastatic disease with a high-level of MET-amplification

**Central Nervous System (CNS) Cancers ‡ [2,4]**

- Patient has MET exon-14 mutated non-small cell lung cancer as detected by an FDA-approved or CLIA compliant test❖; **AND**
    - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
    - Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options; **OR**
    - Patient has recurrent limited brain metastases; **OR**
    - Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options

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

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ 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: interstitial lung disease (ILD), pneumonitis, severe hepatotoxicity (e.g., increased AST, ALT, and/or bilirubin), pancreatic toxicity (e.g., increased amylase/lipase), serious hypersensitivity reactions, severe photosensitivity reactions, etc.

## V. Dosage/Administration [1,4]

| Indication | Dose |
|---|---|
| All Indications | Administer 400 mg orally twice daily until disease progression or unacceptable toxicity. |

## VI. Billing Code/Availability Information

HCPCS Code(s):

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

NDC(s):

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

## VII. References


1. Tabrecta [package insert]. East Hanover, NJ; Novartis Pharmaceuticals, Inc., March 2023. Accessed March 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for capmatinib. National Comprehensive Cancer Network, 2023. 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 March 2023.
3. 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.
4. Wolf J, Seto T, Han JY, et al; GEOMETRY mono-1 Investigators. Capmatinib in MET Exon 14-Mutated or MET-Amplified Non-Small-Cell Lung Cancer. N Engl J Med. 2020 Sep 3;383(10):944-957. doi: 10.1056/NEJMoa2002787.


## 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 |

| ICD-10 | ICD-10 Description |
|---|---|
| C34.92 | Malignant neoplasm of unspecified part of left bronchus or lung |
| C79.31 | Secondary malignant neoplasm of brain |
| Z85.118 | Personal history of other malignant neoplasm of bronchus and 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: https://www.cms.gov/medicare-coverage-database/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 |
| 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 |