Clinical Policy: Capmatinib (Tabrecta)

Reference Number: ERX.SPA.401
Effective Date: 09.01.20
Last Review Date: 08.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Capmatinib (Tabrecta™) is a kinase inhibitor that targets mesenchymal-epithelial transition (MET).

FDA Approved Indication(s)
Tabrecta is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to MET exon 14 skipping as detected by an FDA-approved test.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Tabrecta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of recurrent, advanced or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is positive for a mutation causing MET exon 14 skipping (*see Appendix D*);
5. Disease is epidermal growth factor receptor (EGFR) wild-type and anaplastic lymphoma kinase (ALK) negative;
6. Member does not have symptomatic CNS metastases;
7. For Tabrecta requests, member must use generic capmatinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
8. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg (4 tablets) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 6 months
Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Non-Small Cell Lung Cancer (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Tabrecta for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 800 mg (4 tablets) per day;
   b. New dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;
B. Positive MET amplification WITHOUT an Exon 14 skipping mutation.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MET: mesenchymal-epithelial transition
NSCLC: non-small cell lung cancer
EGFR: epidermal growth factor receptor
ALK: anaplastic lymphoma kinase

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information

- Mutation causing MET exon 14 skipping:
  - The test is interpreted by the pathologist that signs the report.
  - The ONLY test that should be POSITIVE is the presence of an Exon 14 Skipping Mutation for the MET gene.
  - The following results should be considered NEGATIVE:
    - Presence of MET amplification WITHOUT the presence of an Exon 14 skipping mutation of the MET gene;
    - Presence of any other genomic aberration (mutation, deletion, rearrangement) of the MET gene;
    - There exists a potential for abuse/misuse of the drug would be if the patient's tumor had a MET amplification ONLY. The drug was tested AND found to be ineffective in patients whose tumors were positive for the MET amplification WITHOUT an Exon 14 Skipping Mutation. Thus, the drug should NOT be approved for a positive MET amplification WITHOUT an Exon 14 skipping mutation.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	400 mg PO BID	800 mg/day

VI. Product Availability

Tablets: 150 mg, 200 mg

VII. References

1. Tabrecta Prescribing Information. East Hanover, NJ; Novartis Pharmaceuticals Corporation: August 2022. Available at: www.us.tabrecta.com. Accessed August 24, 2022.
2. Capmatinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 3, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06.09.20	08.20
3Q 2021 annual review: no significant changes; added in Section III: Positive MET amplification WITHOUT an Exon 14 skipping mutation; references reviewed and updated.	04.02.21	08.21
3Q 2022 annual review: no significant changes; added option for recurrent disease per NCCN; references reviewed and updated.	05.03.22	08.22
RT4: NSCLC indication converted to full FDA approval; added standard oral oncology generic redirection language.	08.24.22	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.