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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	May 29, 2020
Subject:	Tabrecta	**Page:**	1 of 5

Last Review Date: March 8, 2024

Tabrecta

Description

Tabrecta (capmatinib)

Background
Tabrecta is a kinase inhibitor that targets mesenchymal-epithelial transition (MET), including the mutant variant produced by exon 14 skipping. MET exon 14 skipping results in a protein with a missing regulatory domain that reduces its negative regulation leading to increased downstream MET signaling. Tabrecta inhibits cancer cell growth driven by a mutant MET variant lacking exon 14 at clinically achievable concentrations and demonstrated anti-tumor activity. Tabrecta inhibits the phosphorylation of MET triggered by binding of hepatocyte growth factor or by MET amplification, as well as MET-mediated phosphorylation of downstream signaling proteins and proliferation and survival of MET-dependent cancer cells (1).

Regulatory Status
FDA-approved indication: Tabrecta is a kinase inhibitor indicated for the 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 (1).

Off Label Use: (2-3)
1. NSCLC tumors with high-level MET amplification

Tabrecta can cause Interstitial Lung Disease (ILD)/Pneumonitis. Patients taking Tabrecta should be monitored for new or worsening pulmonary symptoms indicative of ILD/pneumonitis.

Tabrecta should be permanently discontinued if no other potential causes of ILD/pneumonitis are identified (1).

Tabrecta can cause hepatotoxicity. Liver function tests (including ALT, AST, and total bilirubin) should be monitored prior to the start of Tabrecta, every 2 weeks during the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop increased transaminases or bilirubin. Tabrecta should be withheld, have dose reduced, or permanently discontinued based on severity (1).

Tabrecta can cause fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised to use effective contraception during treatment with Tabrecta and for 1 week after the last dose. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Tabrecta and for 1 week after the last dose (1).

The safety and effectiveness of Tabrecta in pediatric patients have not been established (1).

Related policies
Tepmetko

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tabrecta may be considered **medically necessary** if the conditions indicated below are met.

Tabrecta may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Metastatic non-small cell lung cancer (NSCLC)

AND ALL of the following:

a. Tumor specimens show **ONE** of the following:
    i. High-level mesenchymal-epithelial transition (MET) amplification
    ii. MET exon 14 skipping as detected by an FDA-approved test
b. Prescriber agrees to monitor for new or worsening pulmonary symptoms indicative of interstitial lung disease (ILD)/pneumonitis
c. Patient has had baseline liver function tests (LFTs) performed before starting Tabrecta and prescriber agrees to monitor LFTs
d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Tabrecta and for 1 week after the last dose
e. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Tabrecta and for 1 week after the last dose

Prior–Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Metastatic non-small cell lung cancer (NSCLC)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor for new or worsening pulmonary symptoms indicative of interstitial lung disease (ILD)/pneumonitis
c. Prescriber agrees to monitor liver function tests (LFTs)
d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Tabrecta and for 1 week after the last dose

e. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Tabrecta and for 1 week after the last dose

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity 336 tablets per 84 days

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Tabrecta (capmatinib) is a kinase inhibitor indicated for the 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. In addition, the National Comprehensive Cancer Network (NCCN) Guidelines support the off-label use of Tabrecta for metastatic NSCLC with high-level MET amplification. Tabrecta has warnings for interstitial lung disease (ILD)/pneumonitis, hepatotoxicity, risk of photosensitivity, and embryo-fetal toxicity. The safety and effectiveness of Tabrecta in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Tabrecta while maintaining optimal therapeutic outcomes.

References

1. Tabrecta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2023.

2. NCCN Clinical Practice Guidelines in Oncology® Non-Small Cell Lung Cancer (Version 1.2024). National Comprehensive Cancer Network, Inc. December 2023. Accessed on January 16, 2024.
3. NCCN Drugs & Biologics Compendium® Capmatinib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 16, 2024.

Policy History

Date	Action
May 2020	Addition to PA
September 2020	Annual review
June 2021	Annual editorial review and reference update
February 2022	Per FEP, addition of NCCN off-label indication: NSCLC tumors with high-level MET amplification
March 2022	Annual review and reference update
December 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.