BlueCross BlueShield
Federal Employee Program

TABRECTA
(capmatinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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 2024.
2. NCCN Clinical Practice Guidelines in Oncology® Non-Small Cell Lung Cancer (Version 3.2025). National Comprehensive Cancer Network, Inc. January 2025. Accessed on January 14, 2025.
3. NCCN Drugs & Biologics Compendium® Capmatinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.