

Clinical Pharmacy Program Guidelines for Tabrecta

Program	Prior Authorization
Medication	Tabrecta™ (capmatinib)
Markets in Scope	Arizona, California, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	7/2020
Pharmacy and Therapeutics Approval Date	7/2020
Effective Date	9/2020

1. Background:

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.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

The National Cancer Comprehensive Network (NCCN) guideline also recommends use of Tabrecta as single-agent therapy for recurrent, advanced or metastatic disease in patients with MET exon 14 skipping positive tumors.

1. Coverage Criteria:

<p>A. <u>Non-Small Cell Lung Cancer (NSCLC)</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Tabrecta will be approved based on <u>all</u> of the following criteria:</p> <p>(1) Diagnosis of non-small cell lung cancer (NSCLC)</p> <p align="center">-AND-</p> <p>(2) Disease is <u>one</u> of the following:</p> <p>(a) Recurrent</p> <p>(b) Advanced</p> <p>(c) Metastatic</p>
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-AND-

- (3) Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors

Authorization will be issued for 12 months.

2. Reauthorization

- a. **Tabrecta** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Tabrecta therapy

Authorization will be issued for 12 months.

B. NCCN Recommended Regimens

1. Initial Authorization

- a. **Tabrecta** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

- a. **Tabrecta** will be approved based on the following criterion:

- (1) Documentation of positive clinical response to Tabrecta therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Tabrecta [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation, May 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed May 22, 2020

Program	Program type – Prior Authorization
Change Control	
7/2020	New program.