UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1321-5
Program	Prior Authorization/Notification
Medication	Tabrecta® (capmatinib)
P&T Approval Date	7/2020, 7/2021, 7/2022, 7/2023, 7/2024
Effective Date	10/1/2024

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.

The National Cancer Comprehensive Network (NCCN) guideline also recommends use of Tabrecta as single-agent therapy for NSCLC with high-level MET amplification.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Non-Small Cell Lung Cancer (NSCLC)</u>

1. **<u>Initial Authorization</u>**

   a. **Tabrecta** will be approved based on **all** of the following criteria:

      (1) **<u>Both</u>** of the following:

         (a) Diagnosis of non-small cell lung cancer (NSCLC)

         -AND-

         (b) **<u>One</u>** of the following:

i. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors
ii. High level MET amplification in lung cancer

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.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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, March 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed June 4, 2024.

Program	Prior Authorization/Notification – Tabrecta® (capmatinib)
Change Control	
7/2020	New program.
7/2021	Updated coverage criteria for NSCLC according to NCCN guidelines.
7/2022	Annual review. Added state mandate with no other changes to criteria. Updated references.
7/2023	Annual review. Updated background with FDA regular approval. Updated references.
7/2024	Annual review. Updated references.