

Tabrecta (capmatinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Tabrecta (capmatinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Tabrecta (capmatinib) may be approved if the following criteria are met (Label, NCCN 2A):

- I. Individual has a diagnosis of recurrent, advanced, or metastatic Non-Small Cell Lung Cancer (NSCLC); **AND**
 - A. Individual is using as monotherapy; **AND**
 - B. Individual has mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors with test results confirmed; **AND**
 - C. Individual has not received treatment with another MET exon 14 skipping-targeted agent, such as crizotinib;

OR

- II. Individual has a diagnosis of metastatic Non-Small Cell Lung Cancer with brain metastases and the following criteria are met (NCCN 2A):
 - A. Individual has a primary diagnosis of non-small cell lung cancer; **AND**
 - B. Individual is using as monotherapy;
 - C. Individual has MET exon 14 skipping positive tumors;

OR

- III. Individual has a diagnosis of advanced or metastatic Non-Small Cell Lung Cancer and the following criteria are met (NCCN 2A):
 - A. Individual is using as monotherapy; **AND**
 - B. Individual has high level mesenchymal-epithelial transition (MET) amplification (≥ 10 gene copies) (Wolf 2020).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 20, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 20, 2021.
 - a. Non-Small Cell Lung Cancer. V5.2021. Revised June 15, 2021.
6. NCT02414139. ClinicalTrials.gov. U.S. National Library of Medicine. National Institute of Health. Available at <https://clinicaltrials.gov/ct2/show/NCT02414139?term=nct02414139&draw=2&rank=1>.
7. Wolf J, Seto T, Han JY, et al. Capmatinib in *MET* Exon 14-Mutated or *MET*-Amplified Non-Small-Cell Lung Cancer. *N Engl J Med*. 2020;383(10):944-957. doi:10.1056/NEJMoa2002787 Available at: <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2002787?articleTools=true>. Accessed July 16, 2021.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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