Drug Policy:

Tabrecta™ (capmatinib)

POLICY NUMBER UM ONC_1406	**SUBJECT** Tabrecta™ (capmatinib)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 06/10/20, 06/09/21, 11/15/21, 05/11/22, 06/08/22, 08/09/23, 08/14/24	**APPROVAL DATE** August 14, 2024	**EFFECTIVE DATE** August 30, 2024	**COMMITTEE APPROVAL DATES** 06/10/20, 06/09/21, 11/15/21, 05/11/22, 06/08/22, 08/09/23, 08/14/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Tabrecta (capmatinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The member has not experienced disease progression on the requested medication AND
2. The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
3. Additional medication(s) are not being added to the continuation request.

B. Non-Small Cell Lung Cancer

1. Member has advanced/metastatic Non-Small Cell Lung Cancer that is negative for EGFR and ALK and the tumor is MET mutation positive (specifically an exon 14 skipping mutation of the MET gene as confirmed by the companion diagnostic test FoundationOne CDx assay or an equivalent valid test) AND
2. Tabrecta (capmatinib) is being used as a single agent either as first line/initial therapy or as second/subsequent line of therapy (if not used previously as initial therapy).

III. EXCLUSION CRITERIA

A. Disease progression while receiving Tabrecta (capmatinib) or another MET inhibitor [e.g., Tepmetko (tepotinib)].

B. Concurrent use with other anti-cancer therapy including targeted therapy, chemotherapy, or immunotherapy.

C. Dosing exceeds single dose limit of Tabrecta (capmatinib) 400 mg.

D. Treatment exceeds the maximum limit of 120 (150 mg) or 120 (200 mg) tablets/month.

E. Investigational use of Tabrecta (capmatinib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Wolf J, et al. GEOMETRY mono-1 Clinical Trial. Capmatinib in MET Exon 14-Mutated or MET-Amplified Non-Small-Cell Lung Cancer. N Engl J Med. 2020 Sep 3;383(10):944-957.

B. Tabrecta prescribing information. Novartis Pharmaceuticals Corporation East Hanover, New Jersey 2024.

C. Clinical Pharmacology Elsevier Gold Standard 2024.

D. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2024.

E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.

F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2024.

G. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

H. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

I. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.