Clinical Policy Title:	capmatinib
Policy Number:	RxA.641
Drug(s) Applied:	Tabrecta®
Original Policy Date:	09/14/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all):

1. Diagnosis of recurrent, advanced or metastatic non-small cell lung cancer (NSCLC);
2. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 400 mg twice daily;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA approved or recommended by NCCN.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

B. Central nervous system cancer (off- label) (must meet all):

1. Diagnosis is for one of the following (a or b):
   a. Recurrent or relapsed limited brain metastases with MET exon-14 mutated non-small cell lung cancer;
   b. Recurrent extensive brain metastases with MET exon-14 mutated non-small cell lung cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 400 mg twice daily;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA approved or recommended by NCCN.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for dose increase request meets one of the following (a or b):
   a. New dose does not exceed 400 mg twice daily;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA approved or recommended by NCCN.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. Vansteenkiste J, et al. Capmatinib for the treatment of non-small cell lung cancer. Expert review of Anticancer Therapy. 2019; 19:659-671. doi: 10.1080/14737140. 2019.1643239. Available at: https://pubmed.ncbi.nlm.nih.gov/31368815/. Accessed May 1, 2023.
2. National Comprehensive Cancer Network. Central Nervous System Cancer Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed May 1, 2023.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed May 1, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	07/01/2020	09/14/2020
Policy was reviewed: 1. Clinical Policy Title was updated remove brand “Tabrecta™” for consistency. 2. Clinical Policy Title Line of Business Policy Applies to was updated from “Commercial, Medicaid, Medicare” to “All lines of business”. 3. Initial Approval Criteria I.A.2 was updated to include prescriber criteria “Prescribed by or in consultation with an oncologist;”. 4. Initial Approval Criteria I.A.5 was updated to include “Request meets one of the following (a or b)…”. 5. Initial Approval Criteria I.B was updated to include off-label indication “Central nervous system cancer (off- label)…”. 6. Continued Therapy Approval Criteria II.A was updated from “Non Small Cell Lung	07/08/2021	09/14/2021

Cancer" to "All Indications in Section I (must meet all)…". 7. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 8. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria I.A.4 was added to include criteria "Disease is epidermal growth factor receptor (EGFR) wild-type and anaplastic lymphoma kinase (ALK) negative;". 2. Initial Approval Criteria I.A.6b, I.B.4b, and Continued Therapy Approval Criteria II.A.3b was updated to include requirement "*Prescribed regimen must be FDA approved or recommended by NCCN". 3. References were reviewed and updated.	06/28/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated indication from Diagnosis of 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 to Diagnosis of recurrent, advanced or metastatic non-small cell lung cancer (NSCLC). 2. Initial Approval Criteria, I.A.2: Updated to include new diagnostic criteria Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). 3. Initial Approval Criteria, I.A.4: Updated to remove prior criteria pertaining to indication Metastatic non-small cell lung cancer, "Disease is epidermal growth factor receptor (EGFR) wild-type and	05/01/2023	07/13/2023

anaplastic lymphoma kinase (ALK) negative." 4. Initial Approval Criteria, I.A.5: Updated to remove prior diagnostic criteria "Member has an ECOG performance status of 0 or 1." 5. Initial Approval Criteria, I.A and I.B: Updated approval duration from 3 months to 12 months for Commercial and Medicaid. 6. Continued Therapy Approval Criteria, II.A: Updated approval duration from 6 months to 12 months for Commercial and Medicaid. 7. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023