RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	Capmatinib (Tabrecta)
Policy Number:	RxA.641
Drug(s) Applied:	Tabrecta®
Original Policy Date:	09/14/2020
Last Review Date:	07/01/2020
Line of Business Policy Applies to:	Commercial, Medicaid, Medicare

Background

TABRECTA 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 as detected by an FDA-approved test.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Capmatinib (Tabrecta)	TABRECTA 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 as detected by an FDA-approved test.	400 mg orally twice daily with or without food	400mg twice daily

Dosage Forms

- Tablets: 150 mg and 200 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer

1. The member is 18 years of age or older
2. The member has a 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
3. The member has an ECOG performance status of 0 or 1

Approval Duration: 3 months
Commercial: 3 months
Medicaid: 3 months

II. Continued Therapy Approval

A. Non-Small Cell Lung Cancer

1. The member is currently receiving Retevmo as authorized by RxAdvance or member has previously met initial approval criteria.
2. The member is responding positively to therapy

Approval Duration 6 months
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

1. ECOG: Eastern Cooperative Oncology Group
2. NSCLC: Non-Small Cell Lung Cancer
3. MET: mesenchymal epithelial transition

APPENDIX B: Therapeutic Alternatives

Xalkori (crizotinib) inhibits ALK fusions, ROS1 fusions and some MET tyrosine kinases (high-level MET amplification or METex14 mutation). It is approved by the FDA for patients with metastatic NSCLC who have ALK gene fusion or ROS1 fusions. It is not FDA approved for patients with NSCLC METex14 mutations however it widely used in this patient population.

Tagrisso (osimertinib), although not FDA approved for patients with NSCLC with METex14 mutations, has been used.

Cabometyx (cabozantinib), also not FDA approved for this type of NSCLC, has been studied in METex14 mutated NSCLC.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None

- Boxed Warning(s):
  - None

References

1. Tabreca Prescribing Information. East Hanover, NJ; Novartis: May 2020. Available at www.dayvigo.com. Accessed June 29, 2020.
2. 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

3. Wolf J, et al. Capmatinib (INC280) in METΔex14-mutated advanced non-small cell lung cancer (NSCLC): Efficacy data from the phase II GEOMETRY mono-1 study. Journal of Clinical Oncology. 2019;37(S15):9004. doi: 10.1200/JCO.2019.37. 15_suppl.9004 3.
4. Wang Q, et al. MET inhibitors for targeted therapy of EGFR TKI-resistant lung cancer. Journal of Hematology and Oncology. 2019;12:63. doi: 10.1186/s13045- 019-0759-9

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	07/01/2020	09/14/2020