Clinical Policy Title:	capmatinib
Policy Number:	RxA.641
Drug(s) Applied:	Tabrecta™
Original Policy Date:	09/14/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Capmatinib (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™)	Metastatic NSCLC	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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. 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;
2. Prescribed by or in consultation with an oncologist;
3. Age 18 years of age or older;
4. Member has an ECOG performance status of 0 or 1;
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).

Approval Duration

Commercial: 3 months

Medicaid: 3 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 of age or older;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 400mg twice daily;;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval Duration
Commercial: 3 months
Medicaid: 3 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 400mg 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).

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
ECOG: Eastern Cooperative Oncology Group
NSCLC: Non-Small Cell Lung CancerMET: mesenchymal epithelial transition

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Xalkori®	250 mg orally twice daily	500 mg/day
Tepmetko®	450 mg orally once daily with food until disease progression or unacceptable toxicity	450 mg orally once daily

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by

generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- ECOG Performance Status
  - Grade 0: Fully active, able to carry on all pre-disease performance without restriction.
  - Grade 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work.
  - Grade 2: Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours.
  - Grade 3: Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours.
  - Grade 4: Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
  - Grade 5: Dead.

References

1. Tabrecta Prescribing Information. East Hanover, NJ; Novartis: May 2020. Available at: https://www.novartis.us/sites/www.novartis.us/files/tabrecta.pdf . Accessed July 08, 2021.
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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. Available at: https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.15_suppl.9004. Accessed July 08, 2021.
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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. Dosing Information indication was updated from "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 mesenchymalepithelial…" to "Metastatic NSCLC". 4. Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. 5. Initial Approval Criteria I.A.2 was updated to include prescriber criteria "Prescribed by or in consultation with an oncologist;". 6. Initial Approval Criteria I.A.5 was updated to include "Request meets one of the following (a or b)…". 7. Initial Approval Criteria I.A.5.a was updated to include "Dose does not exceed 400 mg twice daily;". 8. Initial Approval Criteria I.A.5.b was updated to include "Dose is supported by practice guidelines or peer-reviewed literature…". 9. Initial Approval Criteria I.B was updated to include off-label indication "Central nervous system cancer (off- label)…". 10. Continued Therapy Approval Criteria II.A was updated from "Non Small Cell Lung Cancer" to "All Indications in Section I (must meet all)…". 11. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 12. Continued Therapy Approval Criteria II.A.3 was updated to include "If request is for dose increase request meets one of the following (a or b)…".	07/08/2021	09/14/2021

13. Continued Therapy Approval Criteria II.A.3.a was updated to include “New dose does not exceed 400mg twice daily;”. 14. Continued Therapy Approval Criteria II.A.3.b was updated to include “New dose is supported by practice guidelines or peer-reviewed literature…”. 15. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 16. Appendix B: Therapeutic Alternatives was updated to remove statements, “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…”, “Tagrisso (osimertinib), although not FDA approved for patients with NSCLC with METex14 mutations…”, and “Cabometyx (cabozantinib), also not FDA approved for this type of NSCLC, has been studied…”. 17. Appendix B: Therapeutic Alternatives was updated to include brand-name drugs Xalkori and Tepmetko, as well as their respective dosing regimens and dose limits, in table format. 18. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 19. Appendix D was updated to include “ECOG Performance Status” and subsequent Grade 0-5 designations. 20. References were reviewed and updated.		