RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	cobimetinib
Policy Number:	RxA.361
Drug(s) Applied:	Cotellic®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Cobimetinib (Cotellic®) is a kinase inhibitor. Cobimetinib is indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Cobimetinib (Cotellic®)	Melanoma	60 mg (three tablets) PO once daily for 21 days, then off for 7 days (28-day cycle)	60 mg/day

Dosage Forms

- Tablet: 20 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. Melanoma (must meet all)**:**

1. Diagnosis of metastatic or unresectable melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is positive for the BRAF V600E or V600K mutation;
5. Prescribed in combination with Zelboraf®;
6. Dose does not exceed 60 mg/day (3 tablets) per day, for the first 21 days of each 28-day cycle..

Approval duration
Commercial: 12 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Melanoma (must meet all)**:**

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 60 mg/day (3 tablets) per day for the first 21 days of each 28-day cycle.

Approval duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
BRAF: B-Raf proto-oncogene serine/threonine kinase
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported
- Boxed warning(s):
  - None reported

References

1. Cotellic Prescribing Information. South San Francisco, CA: Genentech; January 2018. Available at: https://www.gene.com/download/pdf/cotellic_prescribing.pdf. Accessed July 14, 2020.
2. Zelboraf Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; November 2017. Available at: https://www.gene.com/download/pdf/zelboraf_prescribing.pdf. Accessed July 14, 2020.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 14, 2020.
4. National Comprehensive Cancer Network. Cutaneous Melanoma Version 3.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed July 14, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed. 1. Policy title table was updated 2. Line of Business policy was updated to 'All lines of business'. 3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Initial therapy criteria I.A.6 clarified dosing is limited to the first 21 days of each 28-day cycle. 5. Continued therapy approval duration for Medicaid updated to 12 months. 6. Approval duration for commercial was updated from length of benefit to 12 months. 7. Reference reviewed and updated.	07/14/2020	09/14/2020