

Clinical Policy: Cobimetinib (Cotellic)

Reference Number: ERX.SPA.239

Effective Date: 09.01.18

Last Review Date: 05.20

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

Cobimetinib (Cotellic[®]) is a kinase inhibitor.

FDA Approved Indication(s)

Cotellic is indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib.

Policy/Criteria

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

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions[™] that Cotellic is **medically necessary** when the following criteria are met:

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 \geq 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 (3 tablets) per day, for the first 21 days of each 28-day cycle.

Approval duration:

Medicaid – 6 months

Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Melanoma (must meet all):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Cotellic for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 60 mg (3 tablets) per day, for the first 21 days of each 28-day cycle.

Approval duration:

Medicaid – 12 months

Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents;
- B. Treatment of melanoma in patients with wild type BRAF gene.

IV. Appendices/General Information

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

None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Melanoma	60 mg (three tablets) PO QD for 21 days, then off for 7 days (28 day cycle)	60 mg/day

VI. Product Availability

Tablet: 20 mg

VII. References

1. Cotellic Prescribing Information. South San Francisco, CA: Genentech; January 2018. Available at: https://www.gene.com/download/pdf/cotellic_prescribing.pdf. Accessed February 10, 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 February 10, 2020.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 10, 2020.
4. National Comprehensive Cancer Network. Cutaneous Melanoma Version 1.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed February 10, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.11.18	08.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.26.19	05.19
2Q 2020 annual review: no significant changes; added Medicaid line of business with 6/12 month initial/continued authorization duration; for dosing limits in Section I and II clarified dosing is limited to the first 21 days of each 28-day cycle; references reviewed and updated.	02.10.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2018 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.