Clinical Policy: Cobimetinib (Cotellic)

Reference Number: CP.PHAR.380
Effective Date: 11.16.16
Last Review Date: 05.22
Line of Business: Commercial, HIM, 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.

It is the policy of health plans affiliated with Centene Corporation® 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 ≥ 18 years;
4. Disease is positive for the BRAF V600E or V600K mutation;
5. Prescribed in combination with Zelboraf®;*
   **Prior authorization may be required.*
6. For Cotellic requests, member must use cobimetinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 60 mg (3 tablets) per day, for the first 21 days of each 28-day cycle.

Approval duration:
Medicaid/HIM – 6 months
Commercial – 12 months or duration of request, whichever is less

B. Histiocytic neoplasms (off-label) (must meet all):

1. Diagnosis of one of the following histiocytic neoplasms (a, b, or c):
   a. Langerhans Cell Histiocytosis;
   b. Rosai-Dorfman Disease;
   c. Erdheim-Chester Disease;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;

4. Disease meets one of the following (a, b, or c):
   a. Positive for mitogen-activated protein (MAP) kinase pathway mutation,
   b. No detectable mutation;
   c. Mutation testing not available;
5. For Cotellic requests, member must use cobimetinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 60 mg (3 tablets) per day, for the first 21 days of each 28-day cycle;
   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:
Medicaid/HIM – 6 months
Commercial – 12 months or duration of request, whichever is less

C. Central Nervous System Cancers (off-label) (must meet all):
1. Diagnosis of one of the following (a, b, or c):
   a. Adult low-grade glioma (WHO grade 1 or 2);
   b. Anaplastic glioma;
   c. Glioblastoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is positive for the BRAF V600E mutation;
5. Prescribed in combination with Zelboraf;*

   **Prior authorization may be required.*
6. For Cotellic requests, member must use cobimetinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 60 mg (3 tablets) per day, for the first 21 days of each 28-day cycle;
   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:
Medicaid/HIM – 6 months
Commercial – 12 months or duration of request, whichever is less

D. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Cotellic for melanoma and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Cotellic requests, member must use cobimetinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. Request meets one of the following (a or b):*
   a. Dose does not exceed 60 mg (3 tablets) per day, for the first 21 days of each 28-day cycle;
   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:
Medicaid/HIM – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid 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
WHO: World Health Organization

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 11, 2022.
2. Zelboraf Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; May 2020. Available at: https://www.gene.com/download/pdf/zelboraf_prescribing.pdf. Accessed February 11, 2022.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 11, 2022.
4. National Comprehensive Cancer Network. Central Nervous System Cancers Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed February 11, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: no significant changes; policies combined for Centene Medicaid and Commercial lines of business; age and specialist requirements added; continuation of care statement added; references reviewed and updated.	04.10.18	08.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.26.19	05.19
2Q 2020 annual review: added HIM line of business; revised continuation approval duration from 6 to 12 months; 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
2Q 2021 annual review: oral oncology generic redirection language added; revised reference to HIM off-label use policy from HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	01.14.21	05.21
2Q 2022 annual review: added NCCN-supported indications criteria for histiocytic neoplasms and central nervous system cancers; Commercial approval durations revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated.	02.11.22	05.22

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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 clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.