

Cotellic™ (cobimetinib) (Oral)

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I. Length of Authorization

Coverage is provided for three months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Cotellic 20 mg tablet: 63 tablets per 28 days

B. Max Units (per dose and over time) [Medical Benefit]:

- N/A

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years or older; **AND**
- Baseline left ventricular ejection fraction (LVEF) within normal limits; **AND**

Melanoma†

- Patient has *BRAF*V600 mutation detected by FDA approved test (i.e. COBAS 4800 *BRAF* V600 Mutation Test); **AND**
- Patient's disease is unresectable OR metastatic; **AND**
- Used in combination with vemurafenib; **AND**
 - Used as initial therapy or subsequent therapy (if patient is BRAF/MEK-inhibitor naïve); **OR**
 - Used as re-induction therapy for progression/relapse in patients who had disease control for >3 months after previous therapy with Cotellic
- †FDA Approved Indication(s) ‡Compendia Approved Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria in Section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Left ventricular ejection fraction (LVEF) has not had an absolute decrease from baseline \geq 10% and is not below the lower limit of normal (LLN) and the patient does not have symptomatic LVEF changes.
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: new malignancies, retinopathy and retinal vein occlusion, severe dermatological reactions including photosensitivity reactions, severe hepatotoxicity, rhabdomyolysis, hemorrhagic events, etc.

V. Dosage/Administration

Indication	Dose
Melanoma	60 mg (three 20 mg tablets) orally once daily for the first 21 days of each 28-day cycle

VI. Billing Code/Availability Information

Jcode:

- J8999 – Prescription drug, oral, chemotherapeutic, nos
- C9399 – Unclassified drugs or biologicals (Hospital Outpatient use only)

NDC:

- Cotellic 20 mg tablet – 50242-0717-xx

VII. References

1. Cotellic [package insert]. South San Francisco, CA; Genentech USA, Inc; May 2016. Accessed August 2017.
2. Zelboraf [package insert]. South San Francisco, CA; Genentech USA, Inc; September 2017. Accessed September 2017.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) cobimetinib. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2017.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.11	Malignant melanoma of right eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C79.31	Secondary malignant neoplasm of brain
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
Z85.820	Personal history of malignant melanoma of skin

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC