

## Cotellic® (cobimetinib) (Oral)

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### I. Length of Authorization

Coverage is provided for six 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]:

- 60 mg daily for 21 days in a 28 day cycle

### 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**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., trametinib, encorafenib, dabrafenib, binimetinib, etc.) unless otherwise specified; **AND**

#### Melanoma †

- Patient has BRAF V600E or BRAF V600K mutation as detected by FDA approved test\*; **AND**
- Patient has unresectable or metastatic disease; **AND**
- Used in combination with vemurafenib; **AND**
  - Used as initial therapy or subsequent therapy; **OR**
  - Used as re-induction therapy for progression/relapse in patients who had disease control (i.e., complete response, partial response, or stable disease) for >3 months after previous therapy with cobimetinib or another MEK inhibitor (e.g., trametinib, binimetinib, etc.) ‡

\*<http://www.fda.gov/CompanionDiagnostics>

† 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 identified in Section III; **AND**
- Disease response with treatment defined as 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; **AND**
- 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.

#### Melanoma re-induction therapy (metastatic or unresectable disease)

- Patient has completed initial induction therapy with cobimetinib or another MEK inhibitor (e.g., trametinib, binimetinib, etc.); **AND**
- Used in patients who experienced disease control (i.e., complete response, partial response, or stable disease), but subsequently have disease progression/relapse > 3 months after treatment discontinuation of cobimetinib or another MEK inhibitor

#### 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

##### HCPCS:

- 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; January 2018. Accessed October 2019.
2. Zelboraf [package insert]. South San Francisco, CA; Genentech USA, Inc; November 2017. Accessed October 2019.

3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) cobimetinib. National Comprehensive Cancer Network, 2019. 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 October 2019.

### 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

## 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	Palmetto GBA, 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