



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 1/21/2016
LAST REVIEW DATE: 2/18/2021
LAST CRITERIA REVISION DATE: 2/18/2021
ARCHIVE DATE:

COTELLIC™ (cobimetinib) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** Cotellic (cobimetinib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
 2. Individual is 18 years of age or older
 3. A confirmed diagnosis of **ONE** of the following:
 - a. Unresectable **OR** metastatic melanoma with a BRAF V600E **OR** V600K mutation, in combination with Zelboraf (vemurafenib)
 - b. Melanoma with recurrent brain metastases (limited or extensive)
 - c. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
 4. Cotellic is to be used in combination with Zelboraf (vemurafenib)
 5. **ALL** of the following baseline tests have been completed before initiation of treatment:
 - a. Left ventricular ejection fraction (LVEF) is above institutional lower limit or \geq 50%
 - b. Liver function test
 - c. Creatine phosphokinase (CPK)
 - d. Serum creatinine

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Cotellic (cobimetinib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
 2. Individual's condition has not worsened while on therapy
 - a. Worsening is defined as:
 - i. Cancer progression
 3. Individual has been adherent with the medication
 4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
 - a. Significant adverse effects include:
 - i. Hemorrhage
 - ii. Cardiomyopathy



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- iii. Retinopathy or RVO
- iv. Hepatotoxicity
- v. Rhabdomyolysis
- vi. Photosensitivity

5. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Cotellic (cobimetinib) is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with Zelboraf (vemurafenib). It is not indicated for treatment of patients with wild-type BRAF melanoma.

Cobimetinib is a reversible inhibitor of mitogen-activated protein kinase (MAPK)/extracellular signal regulated kinase 1 (MEK1) and MEK2. The MEK proteins are upstream regulators of the extracellular signal related kinase (ERK) pathway, which promotes cellular proliferation. BRAF V600E and V600K mutations result in constitutive activation of the BRAF pathway which includes MEK1 and MEK2.

Cobimetinib and vemurafenib target two different kinases in the RAS/RAF/MEK/ERK pathway. Compared to either drug alone, co-administration results in increased apoptosis and reduced tumor growth in tumor cell lines harboring BRAF V600E mutations.

Cobimetinib is the second MEK inhibitor approved in the United States. The other available MEK inhibitor is Mekinist (trametinib), which is given simultaneously with Tafinlar (dabrafenib), a BRAF inhibitor. BRAF inhibitors [Tafinlar (dabrafenib), Zelboraf (vemurafenib)] or BRAF inhibitors combined with MEK inhibitors may be used as therapies for unresectable or metastatic melanoma when BRAF V600E or V600K mutations are present. These mutations appear in approximately half of malignant melanomas.

Resources:

Cotellic (cobimetinib) product information, revised by Genentech, Inc. 01-2018, at DailyMed <http://dailymed.nlm.nih.gov>. Accessed January 30, 2021.

Cotellic (cobimetinib). National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. 2021; Available at: <http://www.nccn.org>. Accessed January 30, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.