VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Cotellic® (cobimetinib tablets – Genentech/Roche)

TAC APPROVAL DATE: 06/18/2019

OVERVIEW

Cotellic is a mitogen-activated extracellular signal regulated kinase (MEK) inhibitor indicated in combination with Zelboraf® (vemurafenib tablets), for the treatment of patients with unresectable or metastatic melanoma with the *BRAF V600E* or *V600K* mutation.[1] Some mutations in the BRAF gene can result in constitutively activated BRAF kinases that may stimulate tumor cell growth. Cotellic is a reversible inhibitor of mitogen-activated protein kinase (MAPK)/MEK1 and MEK2. Some mutations (e.g., V600E) in the BRAF gene can result in constitutively activated BRAF kinases that may stimulate tumor cell growth and lead to activation of the BRAF pathway, including MEK1 and MEK2.

Disease Overview

Mutations in the BRAF gene are common in several types of cancer.[2] The BRAF protein is normally switched on and off in response to signals that control cell growth and development; however, mutations cause the BRAF protein to be continuously active. This over activity may contribute to the growth of cancers by allowing abnormal cells to grow and divide uncontrollably. The V600E mutation is the most common *BRAF* gene mutation identified in cancers, particularly in melanoma.

Guidelines

NCCN guidelines for melanoma (version 2.2019 – March 12, 2019) recommend BRAF + MEK inhibitor combinations (e.g., Zelboraf + Cotellic, Tafinlar + Mekinist, Braftovi + Mektovi) for first-line (preferred if clinically needed for early response) and subsequent treatment of metastatic or unresectable melanoma with a V600 activating mutation.[3] While combination BRAF/MEK inhibition is preferred, NCCN notes that if contraindicated, monotherapy with a BRAF inhibitor (Tafinlar or Zelboraf) are recommended options, particularly for patients who are not appropriate candidates for checkpoint immunotherapy. Tafinlar + Mekinist is also recommended in guidelines as adjuvant therapy (including for nodal recurrance) in some patients with Stage III disease, including use post-surgery or use after complete lymph node dissection.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Cotellic. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cotellic is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Melanoma.** Approve Cotellic for 3 years if the patient meets ALL of the following (A, B, and C):
   - **A)** The patient has unresectable, advanced, or metastatic melanoma; AND
   - **B)** The patient has *BRAF V600* mutation-positive disease; AND
   - **C)** Cotellic is being prescribed in combination with Zelboraf (vemurafenib tablets).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Cotellic has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Cotellic™ tablets [prescribing information]. South San Francisco, CA: Genentech USA Inc./Roche; January 2018.
2. Genetic Home Reference. BRAF gene. National Institutes of Health, US Department of Health & Human Service Web Site. Reviewed August 2018. Accessed on June 4, 2019. Available at: https://ghr.nlm.nih.gov/gene/BRAF.
3. The NCCN Melanoma Clinical Practice Guidelines in Oncology (Version 2.2019 – March 12, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on June 4, 2019.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
Annual revision	Remove solid tumors other than melanoma from the conditions not recommended for coverage.	09/20/2017
Selected revision	Adjust melanoma criteria to remove "unresectable or metastatic" as a qualifier for melanoma and move to criteria section for initial therapy; add that "advanced" melanoma may be included in this criterion.	12/06/2017
Early annual revision	Remove continuation criteria in melanoma; now all approvals require that the Cotellic is taken in combination with Zelboraf AND that the patient has unresectable, advanced, or metastatic melanoma with a BRAF mutation.	05/23/2018
Annual revision	No criteria changes.	06/18/2019

* For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx; TAC – Therapeutic Assessment Committee; -- Not applicable.