PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Cotellic Prior Authorization Policy
- Cotellic® (cobimetinib tablets – Genentech/Roche)

REVIEW DATE: 07/08/2020

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]

Guidelines
NCCN guidelines for melanoma (version 3.2020 – May 18, 2020) recommend BRAF/MEK inhibitor combinations for first-line (preferred if clinically needed for early response) and subsequent treatment of metastatic or unresectable melanoma with a *V600* activating mutation.[2] While combination BRAF/MEK inhibition is preferred, if a combination is contraindicated, monotherapy with a BRAF inhibitor (Tafinlar® [dabrafenib capsules] or Zelboraf® [vemurafenib tablets]) is recommended option, particularly if the patient is not a candidate for checkpoint immunotherapy. Following resection of limited metastatic disease with a *BRAF V600*-activating mutation, BRAF/MEK combination therapy is among the treatment options for patients with no evidence of disease. Tafinlar + Mekinist® (trametinib tablets) is also recommended in guidelines as adjuvant therapy (including for nodal recurrence) in some patients with Stage III disease, including use post-surgery or use after complete lymph node dissection. If unacceptable toxicity to Tafinlar/Mekinist, other BRAF/MEK combinations can be considered.

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)** Patient has unresectable, advanced, or metastatic melanoma; AND
   - **B)** Patient has *BRAF V600* mutation-positive disease; AND
   - **C)** Cotellic is being prescribed in combination with Zelboraf (vemurafenib tablets).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Cotellic is not recommended in the following situations:

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. The NCCN Melanoma Clinical Practice Guidelines in Oncology (Version 3.2020 – May 18, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 2, 2020.