

SPECIALTY GUIDELINE MANAGEMENT

COTELLIC (cobimetinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Cotellic is indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Authorization for 12 months may be granted for treatment of unresectable or metastatic melanoma when all of the following criteria are met:

- A. Cotellic is used in combination with vemurafenib
- B. Tumor is positive for BRAF V600E or V600K mutation

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Cotellic [package insert]. South San Francisco, CA: Genentech USA, Inc.; May 2016.
2. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed December 02, 2016.