## COBIMETINIB

| Generic | Brand | HICL | GCN | Exception/Other |
|---|---|---|---|---|
| COBIMETINIB FUMARATE | COTELLIC | 42796 | | |

### GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and have **ALL** of the following criteria been met?
   - Positive for BRAF V600E **OR** V600K mutation
   - Cobimetinib will be used in combination with vemurafenib (Zelboraf)

   If yes, **approve for 12 months by HICL with a quantity limit of #63 tablets per 28 days.**
   If no, do not approve.
   **DENIAL TEXT:** Our guideline for **COBIMETINIB (Cotellic)** requires a diagnosis of unresectable or metastatic melanoma. In addition, all of the following criteria must be met:
   - Positive for BRAF V600E **OR** V600K mutation, and
   - Cobimetinib will be used in combination with vemurafenib (Zelboraf).

### RATIONALE
To ensure appropriate use of Cotellic consistent with FDA approved indication.

### FDA APPROVED INDICATION
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 vemurafenib. Cotellic is not indicated for treatment of patients with wild-type BRAF melanoma.

### DOSAGE
The recommended dose is 60 mg orally once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity.

### AVAILABLE STRENGTHS:
- 20 mg tablet

### REFERENCES
- Cotellic [Prescribing Information]; San Francisco, CA: Genentech USA, Inc.; November 2015.

| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 04/01/16
Created: 11/15
Client Approval: 02/16
P&T Approval: 02/16