UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Cotellic

Program	Prior Authorization
Medication	Cotellic® (cobimetinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	8/2016
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

1. Background:

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).[1] The National Cancer Comprehensive Network (NCCN) also recommends the use of Cotellic in combination with Zelboraf® (vemurafenib) as treatment for Central Nervous System (CNS) Cancers.

2. Coverage Criteria:

A. Melanoma

1. Initial Authorization

a. **Cotellic** will be approved based on **all** of the following criteria:

(1) Diagnosis of melanoma

-AND-

(2) Disease is **one** of the following:

(a) Unresectable
(b) Metastatic

-AND-

(3) Disease is positive for **one** of the following mutations:

(a) BRAF V600E

(b) BRAF V600K

-AND-

(4) Used in combination with Zelboraf (vemurafenib)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Cotellic** will be approved based on **both** of the following criterion:

(1) Patient does not show evidence of progressive disease while on Cotellic therapy

-AND-

(2) Used in combination with Zelboraf (vemurafenib)

Authorization will be issued for 12 months.

B. Central Nervous System (CNS) Cancers

1. Initial Authorization

a. Cotellic will be approved based on **all** of the following criteria:

(1) Diagnosis of CNS Cancer

-AND-

(2) Primary disease (melanoma) is responsive to Cotellic therapy

-AND-

(3) Disease is positive for **one** of the following mutations:

(a) BRAF V600E
(b) BRAF V600K

-AND-

(4) Used in combination with Zelboraf (vemurafenib)

Authorization will be issued for 12 months.

2. Reauthorization

a. Cotellic will be approved based on **both** of the following criterion:

(1) Patient does not show evidence of progressive disease while on Cotellic therapy

-AND-

(2) Used in combination with Zelboraf (vemurafenib)

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Cotellic** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Cotellic** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Cotellic therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Cotellic [package insert]. Genentech USA, Inc.: South San Francisco, CA; January 2018.

2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed October 1, 2020.

Program	Prior Authorization –Cotellic (cobimetinib)
Change Control	
Date	Change
8/2016	New program
12/2016	Added criteria to use in combination with Zelboraf. Updated references.
12/2017	Annual Review. Updated References.
11/2018	Added coverage for CNS cancers and NCCN Recommended Regimen review criteria. Updated background and references.
11/2019	Annual review. Added “in combination with Zelboraf” to continuation therapy. Updated references.
11/2020	Annual review. Updated background to match coverage criteria. No change in coverage criteria. Updated references. Added Additional Clinical Rules section.