UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1175-7
Program	Prior Authorization/Notification
Medication	Cotellic® (cobimetinib)
P&T Approval Date	1/2016, 12/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021
Effective Date	2/1/2022; Oxford only: 2/1/2022

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 and for the treatment of histiocytic neoplasms.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria:

A. Patients less than 19 years of age

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. 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.

C. 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) Disease is metastatic, recurrent, progressive or in an inaccessible location

-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 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.

D. Histiocytic Neoplasms

1. Initial Authorization

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

(1) Dignosis of **one** of the following:
(a) Langerhans Cell Histiocytosis
(b) Erdheim-Chester Disease
(c) Rosai-Dorfman Disease

-AND-

(2) **One** of the following:
(a) Mitogen-activated protein (MAP) kinase pathway mutation
(b) No detectable mutation
(c) Testing not available

Authorization will be issued for 12 months.

2. Reauthorization

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

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

Authorization will be issued for 12 months.

E. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

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 September 21, 2021.

Program	Prior Authorization/Notification – Cotellic (cobimetinib)
Change Control	
1/2016	New program.
12/2016	Annual Review. Added criteria to use in combination with Zelboraf. Updated references.
11/2017	Annual Review. Updated references.
11/2018	Annual review. Added coverage for CNS cancers per NCCN guidelines. Updated background and references.
11/2019	Annual review. Added in combination with Zelboraf (vemurafenib) to continuation therapy. Added NCCN recommended regimens criteria. Updated references.
11/2020	Annual review. Updated background to match coverage criteria. No change in coverage criteria. Updated references.
11/2021	Annual review. Updates per NCCN recommendations to CNS cancer and histiocytic neoplasms. Updated reference.