UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1175-10
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, 11/2022, 11/2023, 11/2024
Effective Date	2/15/2025

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) and as a single agent for the treatment of patients with histiocytic neoplasms.[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.

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]:

A. <u>Patients less than 19 years of age</u>

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. <u>Melanoma</u>

1. **<u>Initial Authorization</u>**

   a. **Cotellic** will be approved based on <u>all</u> of the following criteria:

      (1) Diagnosis of melanoma

      -AND-

      (2) **<u>One</u>** of the following:

(a) Patient has unacceptable toxicities to Tafinlar (dabrafenib) or Mekinist (trametinib) on the basis of agent side-effect profile

-OR-

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

i. Relapsed > 3 months after treatment discontinuation
ii. Unresectable
iii. 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 criteria:

(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 **one** of the following:

(a) Circumscribed glioma

(b) Glioblastoma

(c) Limited brain metastases

(d) Extensive brain metastases

-AND-

(2) Disease is BRAF V600E positive

-AND-

(3) 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 the following criterion:

(1) Diagnosis of **one** of the following histiocytic neoplasms:

(a) Langerhans cell histiocytosis
(b) Erdheim-Chester disease

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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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; May 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed September 25, 2024.

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.
11/2022	Annual review. Updated CNS cancer criteria removing BRAF V600K to align with NCCN recommendations. Added state mandate footnote. Updated references.
11/2023	Annual review. Updated histiocytic neoplasms criteria based on labeled indication and CNS cancer based on NCCN recommendations. Updated background and references.
11/2024	Annual review. Updated melanoma, central nervous system cancers,

	and histiocytic neoplasms criteria based on NCCN guidelines.