



PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – MEK Inhibitor) – Cotellic Prior Authorization Policy

- Cotellic® (cobimetinib tablets – Genentech/Roche)

REVIEW DATE: 08/20/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Cotellic is a MEK inhibitor indicated for the following uses:

- **Histiocytic neoplasms**, as a single agent in adults.
- **Melanoma**, in combination with Zelboraf® (vemurafenib tablets), for the treatment of unresectable or metastatic disease with the *BRAF V600E* or *V600K* mutation in adults.¹

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines support use in multiple cancers.⁵

- **Central Nervous System Cancers:** NCCN guidelines (version 1.2025 – June 3, 2025) recommend a BRAF/MEK inhibitor combination (i.e., Tafinlar® [dabrafenib capsules]/Mekinist® [trametinib tablets] or Zelboraf/Cotellic) for treatment of *BRAF V600E* activation mutations in the following situations:

adjuvant treatment (category 2A) of pilocytic astrocytoma, pleomorphic xanthoastrocytoma, or circumscribed ganglioglioma/neuroglioma/glioneuronal tumor; recurrent or progressive circumscribed glioma, pleomorphic xanthoastrocytoma/glioneuronal tumors, high-grade glioma, and recurrent glioblastoma (all category 2A).⁴ Zelboraf/Cotellic combination therapy is also recommended for melanoma with brain metastases (category 2B).

- **Histiocytic Neoplasms:** NCCN guidelines (version 1.2025 – June 20, 2025) recommend Cotellic (preferred) or Mekinist (other recommended regimen) for histiocytic neoplasms (if there is a MAP kinase pathway mutation, or no detectable mutation, or testing is not available) for the following types: Langerhans cell histiocytosis (including multisystem, pulmonary, bone disease, central nervous system lesions, or relapsed or refractory disease), Erdheim-Chester disease, and Rosai-Dorfman disease (all category 2A).³
- **Melanoma, Cutaneous:** NCCN guidelines (version 2.2025 – January 28, 2025) for cutaneous disease recommend BRAF/MEK inhibitor combinations for first-line as “Other Recommended Regimen” (category 1) and subsequent treatment (category 2A) for metastatic or unresectable melanoma with a BRAF V600-activating mutation.² Zelboraf + Cotellic + Tecentriq (atezolizumab intravenous infusion) is a recommended combination that is “useful in certain circumstances” as subsequent therapy (category 2A). The combinations are also recommended for adjuvant treatment (category 2B). While combination BRAF/MEK inhibition is preferred, if a combination is contraindicated, monotherapy with a BRAF inhibitor is an option, especially in patients who are not appropriate candidates for checkpoint immunotherapy.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Cotellic. All approvals are provided for the duration noted below.

- **Cotellic® (cobimetinib tablets – Genentech/Roche)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. Histiocytic Neoplasm. Approve for 1 year if the patient meets BOTH of the following (A and B):

A) Patient is \geq 18 years of age; AND

B) Patient meets ONE of the following (i, ii, or iii):

i. Patient has Langerhans cell histiocytosis; OR

ii. Patient has Erdheim-Chester disease; OR

iii. Patient has Rosai-Dorfman disease.

2. Melanoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A)** Patient is \geq 18 years of age; AND
- B)** Patient has unresectable, advanced, or metastatic melanoma; AND
- C)** Patient has *BRAF V600* mutation-positive disease; AND
- D)** The medication is prescribed in combination with Zelboraf (vemurafenib tablets).

Other Uses with Supportive Evidence

3. Central Nervous System Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A)** Patient is \geq 18 years of age; AND
- B)** The medication is being used for ONE of the following (i, ii, or iii):
 - i.** Adjuvant treatment of ONE of the following (a, b, or c):
 - a)** Pilocytic astrocytoma; OR
 - b)** Pleomorphic xanthoastrocytoma; OR
 - c)** Circumscribed ganglioglioma, or neuroglioma, or glioneuronal tumor; OR
 - ii.** Recurrent or progressive disease for ONE of the following (a, b, or c):
 - a)** High-grade glioma; OR
 - b)** Circumscribed glioma; OR
 - c)** Glioblastoma; OR
 - iii.** Brain metastases due to melanoma; AND
- C)** Patient has *BRAF V600* mutation-positive disease; AND
- D)** The medication is prescribed in combination with Zelboraf (vemurafenib tablets).

CONDITIONS NOT COVERED

- **Cotellic® (cobimetinib tablets – Genentech/Roche)** is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Cotellic® tablets [prescribing information]. South San Francisco, CA: Genentech/Roche; May 31, 2023.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (version 2.2025 – January 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 15, 2025.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2025 – June 20, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 15, 2025.
4. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 1.2025 – June 3, 2025) © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 15, 2025.
5. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 15, 2025. Search terms: cobimetinib.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	07/19/2023
Annual Revision	Central Nervous System Cancer: For adjuvant treatment criteria, specified ganglioma to be "Circumscribed ganglioglioma, or neuroglioma, or glioneuronal tumor". For recurrent or progressive disease criteria, deleted isocitrate dehydrogenase 2-mutant astrocytoma and oligodendroglioma. Specified glioma as "High grade glioma" and added "Circumscribed glioma".	08/14/2024
Update	04/08/2025: The policy name was changed from "Oncology – Cotellic PA Policy" to "Oncology (Oral – MEK Inhibitor) – Cotellic PA Policy".	N/A
Annual Revision	Histiocytic Neoplasm: The requirement that the patient has multisystem disease, pulmonary disease, or central nervous system lesions was removed.	08/20/2025

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