PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Cotellic Prior Authorization Policy
- Cotellic® (cobimetinib tablets – Genentech/Roche)

REVIEW DATE: 08/14/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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:** Guidelines (version 2.2024 – July 25, 2024) 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 adults 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 xanthoastroctyoma/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).

- **Melanoma, Cutaneous:** Guidelines (version 2.2024 – April 3, 2024) for cutaneous disease recommend BRAF/MEK inhibitor combinations for first-line (category 1 "Other Recommended Regimen") and subsequent treatment (category 2A) of metastatic or unresectable melanoma with a *V600*-activating mutation.[2] 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.
- **Histiocytic Neoplasms:** Guidelines (version 2.2024 – July 19, 2024) 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 or central nervous system lesions), Erdheim-Chester disease, and Rosai-Dorfman disease (all category 2A).[3]

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 ≥ 18 years of age; AND
   B) Patient meets one of the following (i, ii, or iii):
      i. Patient has Langerhans cell histiocytosis and ONE of the following (a, b, or c):
         a) Multisystem disease; OR
         b) Pulmonary disease; OR
         c) Central nervous system lesions; 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 ≥ 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 ≥ 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 conditions (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 experimental, investigational or unproven for ANY other use(s) including the following; 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 2.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on August 10, 2024.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – July 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on August 10, 2024.
4. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 2.2024 – July 25, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on August 10, 2024.
5. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 10, 2024. Search terms: encorafenib.

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