

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Cotellic Prior Authorization Policy

- Cotellic® (cobimetinib tablets – Genentech/Roche)

REVIEW DATE: 08/03/2022

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 adults with unresectable or metastatic disease with the *BRAF V600E* or *V600K* mutation.¹

Guidelines

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

- **Central Nervous System Cancers:** Guidelines (version 1.2022 – June 2, 2022) recommend a BRAF/MEK inhibitor combination (i.e., Tafenlar® [dabrafenib capsules]/Mekinist® [trametinib tablets] or Zelboraf/Cotellic) for treatment of *BRAF V600E* activation mutations in adults in the following situations: adjuvant treatment of pilocytic astrocytoma, pleomorphic xanthoastrocytoma, or ganglioglioma; recurrent or progressive low-grade glioma; oligodendroglioma, or isocitrate dehydrogenase-2 (*IDH2*)-mutant astrocytoma; and recurrent glioblastoma.⁴ BRAF/MEK combination therapy is also recommended for melanoma with brain metastases.
- **Melanoma, Cutaneous:** Guidelines (version 3.2022 – April 11, 2022) for cutaneous disease recommend BRAF/MEK inhibitor combinations among the preferred therapies for first-line and subsequent treatment of metastatic or unresectable melanoma with a *V600*-activating mutation.² While combination BRAF/MEK inhibition is preferred, if a combination is contraindicated, monotherapy with a BRAF inhibitor is an option. Tafenlar + Mekinist is also recommended in guidelines as adjuvant therapy (including for nodal recurrence) in some patients with Stage III disease, including use post-surgery or use after complete lymph node dissection. If unacceptable toxicity to Tafenlar/Mekinist, other BRAF/MEK combinations can be considered.
- **Histiocytic Neoplasms:** Guidelines (version 1.2022 – May 20, 2022) 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.³

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cotellic is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Histiocytic Neoplasm.** Approve for 1 year if the patient meets 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 the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has unresectable, advanced, or metastatic melanoma; AND
 - B) Patient has *BRAF V600* mutation-positive disease; AND
 - C) 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 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 situations (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) Ganglioglioma; OR
 - ii. Recurrent or progressive disease for one of the following conditions (a, b, c, or d):
 - a) Glioma; OR
 - b) Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma; OR
 - c) Oligodendroglioma; OR
 - d) 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 RECOMMENDED FOR APPROVAL

Coverage of Cotellic is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.
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REFERENCES

1. Cotellic® tablets [prescribing information]. South San Francisco, CA: Genentech/Roche; October 2022.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (version 2.2021 – February 19, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed on July 27, 2021.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2022 – May 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed on July 30, 2022.
4. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 1.2022 – June 2, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org/>. Accessed on July 30, 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Melanoma: A requirement was added that the patient is ≥ 18 years of age. Central Nervous System Cancer: This condition of approval was added. Histiocytic Neoplasm: This condition of approval was added.	08/04/2021
Selected Revision	Approval durations were changed from 3 years to 1 year.	06/22/2022
Annual Revision	Central Nervous System Cancer: To align with guidelines, criteria for recurrent disease now also apply for progressive disease. For a patient with glioma, the qualifier of “low grade” was removed. To align with guidelines, anaplastic glioma was removed and replaced with isocitrate dehydrogenase-2-mutant astrocytoma or oligodendroglioma. The requirement that the patient has a <i>BRAF V600</i> mutation-positive disease was removed.	08/03/2022
Update	Histiocytic Neoplasm: This condition was moved from the Other Uses with Supportive Evidence to the FDA-Approved Indications section of the policy. There were no criteria changes.	12/08/2022