Reference number(s)
1784-A

Specialty Guideline Management
Cotellic

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Cotellic	cobimetinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

- Cotellic is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib.
- Cotellic is indicated as a single agent for the treatment of adult patients with histiocytic neoplasms.

Compendial Uses[2-8]

- Glioma, BRAF V600 activating mutation-positive
- Meningioma, BRAF V600 activating mutation-positive
- Astrocytoma, BRAF V600 activating mutation-positive
- Cutaneous melanoma

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of BRAF mutation documentation is necessary to initiate the prior authorization review for applicable indications as outlined in the coverage criteria section.

Coverage Criteria

Cutaneous Melanoma[1-4]

Authorization of 12 months may be granted for treatment of BRAF V600 mutation-positive (e.g., BRAF V600E or V600K mutations) cutaneous melanoma in any of the following settings:

- Unresectable or metastatic disease when used in combination with vemurafenib (Zelboraf) with or without atezolizumab (Tecentriq) or atezolizumab and hyaluronidase-tqjs (Tecentriq Hybreza).
- Neoadjuvant therapy in combination with vemurafenib (Zelboraf) if immunotherapy is contraindicated when the member has had an unacceptable toxicity to dabrafenib (Tafinlar) in combination with trametinib (Mekinist) or dabrafenib/trametinib are less desirable based on side-effect profiles.
- Adjuvant treatment of resected stage III disease in combination with vemurafenib (Zelboraf) when the member has had an unacceptable toxicity to dabrafenib (Tafinlar) in combination with trametinib (Mekinist) or dabrafenib/trametinib are less desirable based on side-effect profiles.
- Limited resectable local satellite/in-transit recurrent disease in combination with vemurafenib (Zelboraf) when the member has had an unacceptable toxicity to dabrafenib (Tafinlar) in combination with trametinib (Mekinist) or dabrafenib/trametinib are less desirable based on side-effect profiles.

Central Nervous System Cancer[2,5-8]

Authorization of 12 months may be granted for treatment of BRAF V600 mutation-positive (e.g., BRAF V600E or V600K mutations) gliomas, meningiomas, or astrocytomas.

Histiocytic Neoplasms[1,2]

Authorization of 12 months may be granted for treatment of histiocytic neoplasms (Langerhans cell histiocytosis, Erdheim-Chester disease, Rosai-Dorfman disease) as a single agent.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Cotellic [package insert]. South San Francisco, CA: Genentech USA, Inc.; May 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed November 7, 2024.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous. Version 3.2024. https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed November 7, 2024.
4. Tecentriq Hybreza [package insert]. South San Francisco, CA: Genentech, Inc.; September 2024.
5. Usubalieva A, Pierson CR, Kavran CA, et al. Primary Meningeal Pleomorphic Xanthoastrocytoma With Anaplastic Features: A Report of 2 Cases, One With BRAFV600E Mutation and Clinical Response to the BRAF Inhibitor Dabrafenib. Journal of neuropathology and experimental neurology. 2015;74(10):960-969. doi:10.1097/NEN.0000000000000240.
6. Mordechai O, Postovsky S, Vlodavsky E, et al. Metastatic Rhabdoid Meningioma with BRAF V600E Mutation and Good Response to Personalized Therapy: Case Report and Review of the Literature. Pediatric Hematology and Oncology. 2015; 32:3, 207-211, DOI: 10.3109/08880018.2014.936058
7. Lassaletta, A, Guerreiro Stucklin, A, Ramaswamy, V, et al. Profound clinical and radiological response to BRAF inhibition in a 2-month-old diencephalic child with hypothalamic/chiasmatic glioma. Pediatric Blood and Cancer. 2016; 63: 2038-2041. doi:10.1002/pbc.26086.
8. Meletah SK, Pavlick D, Brennan T, et al. Personalized Treatment for a Patient with a BRAF V600E Mutation using Dabrafenib and a Tumor Treatment Fields Device in a High-Grade Glioma Arising from Ganglioglioma. Journal of the National Comprehensive Cancer Network. 2016; 14(11): 1345-1350.