BlueCross BlueShield Federal Employee Program

COTELLIC
(cobimetinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Cotellic (cobimetinib) is an inhibitor of kinase proteins that are part of the regulation of cellular proliferation, including mitogen-activated protein kinase (MAPK) and extracellular signal regulated kinase 1 and 2 (MEK1 and MEK2). Dysfunction in these pathways has been found to be an important mechanism in cancer cell survival and proliferation (1).

Regulatory Status

FDA-approved indications: Cotellic is a kinase inhibitor indicated: (1)

- For the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib.
- As a single agent for the treatment of histiocytic neoplasms.

New primary malignancies, cutaneous and non-cutaneous can occur with Cotellic. Patients should be monitored for signs and symptoms of both cutaneous and non-cutaneous malignancies. Suspicious skin lesions should be managed by excision and dermopathologic evaluation. Dermatologic monitoring should occur for 6 months following the last dose of Cotellic when administered with vemurafenib (1).

Major hemorrhagic (bleeding) events, severe dermatologic reactions, hepatotoxicity, rhabdomyolysis and severe photosensitivity can occur with Cotellic. Patients should be monitored for hemorrhage, skin abnormalities, liver enzyme abnormalities, creatinine phosphokinase elevations periodically and as clinically indicated. Patients should be advised to avoid sun exposure, wear protective clothing, and use a broad-spectrum UVA/UVB sunscreen (1).

The risk of cardiomyopathy is increased in patients receiving the combination of Cotellic with vemurafenib. The safety of Cotellic has not been established in patients with decreased left ventricular ejection fraction. Left ventricular ejection fraction (LVEF) should be evaluated before treatment, after one month of treatment then every 3 months thereafter during treatment with Cotellic (1).

Prescriber should perform an ophthalmological evaluation at regular intervals and for any visual disturbances. Permanently discontinue Cotellic for retinal vein occlusion (1).

Cotellic can cause fetal harm when administered to a pregnant woman. Females of reproductive potential are advised to use effective contraception during treatment and for 2 weeks following the final dose of Cotellic (1).

Safety and efficacy of Cotellic in patients less than 18 years of age have not been established (1).

Summary

Cotellic (cobimetinib) is a kinase inhibitor targeting the MAPK and MEK proteins. Patients should be monitored for malignancies prior to treatment, during treatment and up to 6 months after final dose. Left ventricular ejection fraction should be monitored prior and during treatment. If the patient experiences severe dermatological reactions, the Cotellic dose should be interrupted, reduced, or discontinued. Cotellic should be permanently discontinued in the event of retinal vein occlusion occurring. Liver function should be monitored during treatment and as clinically indicated. Creatinine phosphokinase should be periodically monitored for signs and symptoms of rhabdomyolysis. The patient should be advised to avoid sun exposure. Female patients of reproductive potential are advised to use effective contraception during treatment and for 2 weeks following the final dose of Cotellic. Safety and efficacy of Cotellic in patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Cotellic while maintaining optimal therapeutic outcomes.

References

1. Cotellic [package insert]. South San Francisco, CA: Genentech USA, Inc.; May 2023.
2. NCCN Drugs & Biologics Compendium® Cobimetinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 24, 2025.