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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Antineoplastic Agents	**Original Policy Date:**	December 11, 2015
Subject:	Cotellic	**Page:**	1 of 4

Last Review Date: March 12, 2021

Cotellic

Description

Cotellic (cobimetinib)

Background
Cotellic (cobimetinib) is indicated for the treatment of patients with metastatic or unresectable melanoma, a type of skin cancer. Cotellic is specifically indicated for the treatment of patients with melanoma whose tumors express a gene mutation called BRAF V600E or V600K. The mutated BRAF protein signals the melanoma cells to replicate faster. Cotellic is taken in combination with vemurafenib. Cotellic and vemurafenib target two different proteins in the cell replication pathway, resulting in cell death and reduction of tumor growth. Cotellic is administered, in combination with vemurafenib, once a day for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity (1).

Regulatory Status
FDA-approved indication: Cotellic is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib (1).

Patients should be monitored for new malignancies prior to initiation of therapy, while on therapy, and for up to 6 months following the last dose of Cotellic (1).

Major hemorrhagic (bleeding) events can occur with Cotellic. Monitor for signs and symptoms of bleeding (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).

Monitor liver laboratory tests during treatment and as clinically indicated (1).

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

Related policies
Braftovi, Mekinist, Mektovi, Tafinlar, Zelboraf

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cotellic may be considered **medically necessary** in patients 18 years of age or older with unresectable or metastatic melanoma and if the conditions indicated below are met.

Cotellic may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Unresectable or metastatic melanoma

AND ALL of the following:

1. Must be used in combination with vemurafenib (Zelboraf)

2. Documented BRAF V600E or V600K mutation as detected by an FDA-approved test.
3. Left ventricular ejection fraction (LVEF) is above 50%

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Unresectable or metastatic melanoma

AND ALL of the following:

1. Must be used in combination with vemurafenib (Zelboraf)
2. Left ventricular ejection fraction (LVEF) is above 50%
3. **NO** disease progression or unacceptable toxicity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 189 tabs per 84 days
Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Cotellic (cobimetinib) is approved for adult patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. 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. Cotellic should be permanently discontinued in the event of retinal vein occlusion occurring. Liver function should be monitored during treatment and as clinically indicated. 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.; January 2018.

Policy History

Date	Action
December 2015	Added to PA
March 2016	Annual review Changed qty limits from 63 tabs per 84days Policy number change from 5.04.68
June 2016	Annual editorial review and reference update Removal of no wild-type BRAF melanoma Change of the assessment of left ventricular ejection fraction (LVEF) by echocardiogram or multigated acquisition (MUGA) scan before initiation and every 3 months to left ventricular ejection fraction (LVEF) is above 50% per SME
September 2016	Annual review
June 2017	Annual editorial review and reference update Addition of age limit to renewal section
June 2018	Annual editorial review and reference update
September 2018	Annual editorial review
June 2019	Annual review
June 2020	Annual review
March 2021	Annual editorial review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.