RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Cotellic is an orally-administered drug used to treat patients with late-stage (metastatic) or unresectable (cannot be removed by surgery) melanoma, the most dangerous 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 and Zelboraf (vemurafenib) target two different proteins in this cell replication pathway, resulting in cell death and reduction of tumor growth. The drug is administered, in combination with Zelboraf (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 (chronic disease of heart muscle) 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 (how well your heart pumps with each beat). 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. Safety and efficacy in pediatric patients below the age of 18 have not been established (1).
Summary
Cotellic is approved for patients 18 years of age or older 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 in pediatric patients below the age of 18 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