

STATE OF MICHIGAN
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES
Before the Director of Insurance and Financial Services

In the matter of:

██████████
Petitioner

v

File No. 154575-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 22nd day of July 2016
by Joseph A. Garcia
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On July 20, 2016, Dr. ██████████, authorized representative of her patient ██████████ (Petitioner), filed a request for an expedited external review with the Director of Insurance and Financial Services under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*, appealing the denial of coverage for a prescription drug. The Petitioner has prescription drug coverage through Blue Cross Blue Shield of Michigan (BCBSM). The benefits are described in BCBSM's *Preferred Rx Program Certificate SG*.

On July 20, 2016, the Director agreed to review BCBSM's coverage denial on an expedited basis after the Petitioner's authorized representative attested that her life or well-being would be jeopardized by the length of time required to perform a standard external review. The Director notified BCBSM of the request and asked for the information used to make its final adverse determination. BCBSM furnished its response and the Director accepted the request for external review.

The Director assigned the case to an independent review organization which provided its analysis and recommendation on July 22, 2016.

II. FACTUAL BACKGROUND

The Petitioner has colon cancer with metastases to the lungs and liver. She also has fatigue, increased bilirubin, and thrombocytopenia. She has been treated, unsuccessfully, with multiple medication therapy. Her oncologist recommended

treatment with the prescription drug Cotellic (cobimetinib) and requested that BCBSM provide coverage for the drug. BCBSM denied the request.

The Petitioner's authorized representative appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated July 18, 2016, affirming its denial. The Petitioner now seeks the Director's review of that adverse determination.

III. ISSUE

Is BCBSM required to provide prescription drug coverage for Cotellic?

IV. ANALYSIS

Respondents' Argument

In its final adverse determination, a BCBSM grievance and appeals coordinator wrote:

You are covered under the *Preferred Rx Program Certificate for Small Groups (SG)*. **Section 2: Prescription Drug Coverage** (Page 11) of the *Certificate* explains the following:

Mandatory Prior Authorization

For some drugs, certain clinical criteria must be met before coverage is provided. In the case of drugs requiring step therapy, for example, previous treatment with one or more preferred drugs may be required. A list of drugs that may require prior authorization or step therapy is available at the BCBSM website at bcbsm.com.

We will pay for each drug and each refill of a drug prescribed by a physician, as follows:

Some drugs require prior authorization from BCBSM before we will pay for them. If prior authorization is not requested or received from us, we will not pay for the drug. You will be responsible for 100 percent of the pharmacy's charge.

We will pay our approved amount for select prescription drugs obtained from a pharmacy or in-network mail order provider if both of the following are met:

- The prescribing physician requests prior authorization and shows that the drug meets BCBSM's prior authorization criteria.

- We approve the request.

For this reason, a Clinical Pharmacist, RPh reviewed the appeal and determined the following:

The coverage guidelines for your Custom Select Drug List benefit require criteria be met before coverage can be authorized. Our criteria for coverage of this medication requires a record (chart notes) that it is being used for the treatment of unresectable or metastatic melanoma in patients with a BRAF V600E or V600K mutation used in combination with Zelboraf (vemurafenib). We have no record (chart notes) that this criteria has been met. Please see National Comprehensive Cancer Network (NCCN) recommendations and pathways for potential treatment options. Consideration for coverage may be given for NCCN recommended therapies or those substantiated by current medical literature

Therefore, prior authorization could not be approved. You will be liable for the charges if the prescription is filled.

Petitioner's Argument

In a July 20, 2016 letter submitted for this review, the Petitioner's oncologist wrote:

[Petitioner] is a 25 year old woman with metastatic colon cancer, with excellent performance status who has exhausted standard therapy and is not a candidate for clinical trials. She developed some BRBPR, a small amount in November 2014. She was referred to GI, and underwent colonoscopy 3/4/2014. This revealed a distal sigmoid mass, and she underwent CT. Findings were consistent with diffuse hepatic metastases, as well as some small non-specific pulmonary nodules.

PATHOLOGY: Colon Sigmoid polypectomy, invasive moderately differentiated adenocarcinoma. Transverse colon adenomatous polyp also noted. P53 was 70% mutated.

She began Folfox chemotherapy 3/2014, and added Avastin cycle #2. Ultimately, she underwent colectomy 8/19/2014. Tumor was NRAS positive, KRAS wild type. Due to progression, she underwent SIRS therapy 9/22/2014, complicated by aseptic cholangitis and severe pain due to the procedure, and she had urgent Cholecystectomy 10/2014. We resumed Folfox 11/2014, and added Avastin back 12/2014. In 1/2015, the pt underwent ALPS with extensive hepatic resection; only the L lateral segment remained. Post-op course was complicated by ascites, ARF, and

need for enteral nutrition.

In 4/2015, CT scans showed increase in number and size of pulmonary nodules, stable ablation cavities in liver. Chemotherapy was delayed due to management of ascites and infection, and in 6/2015 scans showed marked progression in the liver remnant and lungs, and we started 5FU and Avastin resulting in reduced ascites. Subsequently, we reduced to 70% dosing for grade 3 LFT increase and grade 3 thrombocytopenia, after cycle #2. She then had an acute admission 7/2015 for incarcerated hernia, but CT showed good response in the liver. She underwent acute surgical intervention/hernia repair without complication. We resumed chemotherapy 8/20/2015 with 5FU alone, and added Avastin back 9/2015. CT then showed pulmonary progression 11/2015, and we added Oxaliplatin at 50% due to liver function, but progression was documented 1/2016. At that time, she was changed to Irinotecan at 80% dosing, QOW with continued Avastin.

Due to rising CEA, and decreasing liver reserve, thrombocytopenia, 4/12/2016 she was referred to KCC for consideration of clinical trial. Despite a 3-month attempt to get her on two separate phase I studies, she remained ineligible for any trials, including immunotherapy trials, due to liver dysfunction and persistent thrombocytopenia. We did resume Avastin/Irinotecan 5/2016, but she has continued progression.

[Petitioner] maintains an excellent performance status. Pt's tumor was MSI-stable. She has had Foundation One testing, demonstrating NRAS mutation. Studies have demonstrated efficacy of MEK-inhibition in NRAS mutated cancers. Furthermore, recent data was reported combining immunotherapy with MEK-inhibition for MSI-stable metastatic colon cancer, with marked efficacy in RAS-mutated cancers.

Therefore, it is medically necessary for her to receive this treatment, and we are asking for insurance coverage.

Director's Review

To determine whether Cotellic is medically necessary for treatment of the Petitioner's condition, the Director presented the issue to an independent review organization (IRO) for analysis, as required by Section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO reviewer is a physician in active practice for more than ten years who is board certified in hematology and oncology and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the

following analysis and recommendation:

[T]he member has been treated with several prior lines of therapy, including chemotherapy, surgery, and radiation based therapy. She has progression of disease and is felt to have limited treatment options. She was referred for evaluation for a clinical trial and found to be ineligible for multiple trials due to elevated liver function tests and thrombocytopenia. The patient underwent molecular testing from Foundation One and was found to have a NRAS mutation. Treatment with Cotellic (cobimetinib) is requested by her oncologist.

[C]obimetinib is FDA approved for the treatment of unresectable or metastatic melanoma in combination with vemurafenib in patients with a BRAF V600E or V600K mutation. It does not carry a non-FDA approved indication. It is not supported (not mentioned) by the NCCN Guidelines. A search of the medical literature shows only a pilot study and phase I or II clinical trials to support use of cobimetinib or other MEK-inhibitors. Several of these studies showed no benefit of MEK-inhibition in colon cancer patients. The patient's health plan does not support the use of cobimetinib in tumor types other than melanoma, therefore, coverage criteria is not met. In addition, the use of cobimetinib appears to be effective as combination therapy and is the current study of an active phase III clinical trial: A Study to Investigate Efficacy and Safety of Cobimetinib Plus Atezolizumab and Atezolizumab Monotherapy Versus Regorafenib in Participants With Metastatic Colorectal Adenocarcinoma, open or soon to open at 75 sites around the United States. The use of cobimetinib, is at this time, experimental/ investigational for the treatment of NRAS mutated colorectal cancer. It is not medically necessary for the treatment of this patient. The treating oncologist may be able to obtain the drug through expanded access (compassionate use).

[References omitted.]

[T]he Health Plan's criteria for Cotellic are consistent with the current recognized medical standard of care for treatment of the member's medical condition.

Pursuant to the information set forth above and available documentation...Cotellic is not medically necessary for treatment of the member's condition.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the recommendation is afforded deference by the Director. In a decision to uphold or reverse an adverse

determination, the Director must cite "the principal reason or reasons why the [Director] did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b).

The IRO's analysis is based on experience, expertise, and professional judgment. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15). The Director, discerning no reason to reject the IRO's recommendation, finds the prescription drug Cotellic is not medically necessary for treatment of the Petitioner's conditions and, therefore, is not a covered benefit.

V. ORDER

BCBSM's final adverse determination of July 18, 2016, is upheld.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this order may seek judicial review no later than 60 days from the date of this order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Department of Insurance and Financial Services, Office of General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Patrick M. McPharlin
Director

For the Director:



Joseph A. Garcia
Special Deputy Director