

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. 154322-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 27th day of July 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a laboratory and pathology testing by her health plan, Blue Cross Blue Shield of Michigan Mutual Insurance Company (BCBSM).

On June 24, 2016, the Petitioner filed a request with the Director of Insurance and Financial Services for an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* After a preliminary review of the information submitted, the Director accepted the request on July 1, 2016.

The Petitioner receives health care benefits through an individual plan that is underwritten by BCBSM. Her benefits are described in the Blue Cross Premier Silver Benefits Certificate (the certificate).

The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM responded on June 28, 2016, and provided additional information on June 30 and July 7, 2016.

Because the case involves medical issues, it was assigned to an independent medical review organization, which provided its analysis and recommendation to the Director on July 14, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in the *Blue Cross Premier Silver Benefits Certificate* (the certificate).

The Petitioner has a history of microscopic blood in her urine, urgency and pelvic pressure. Her urologist ordered the CxBladder test, a laboratory test for the detection of bladder cancer, and it was performed on August 24, 2015. The charge for this test was \$2,995.00.

BCBSM denied coverage, saying the test was investigational and therefore not a covered benefit.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated April 28, 2016, affirming its denial. The Petitioner now seeks review of that final adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny coverage for the Petitioner's Cxbladder test?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination, BCBSM told the Petitioner:

This letter is in response to an appeal initiated on your behalf by the provider, Pacific Edge Diagnostics, and will inform you of the outcome of your managerial-level conference conducted on April 6, 2016. The purpose of the conference was to discuss denial of payment for laboratory and pathology testing conducted on August 24, 2015. After review, the BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined the Cxbladder testing (procedure code 81479) is investigational. Investigational services are not covered under your health care plan, and as a result,

payment cannot be approved for procedure code 81479 in the amount of \$2,995.00.

* * *

An associate medical director, board-certified D.O. in Internal Medicine reviewed your claim, your appeal and your health care plan benefits for [BCBSM] and determined:

"Your doctor ordered Cxbladder testing. According to the Blue Cross Blue Shield of Michigan medical policy "Urinary Tumor Markers for Bladder Cancer," the assessment of urinary tumor markers using bladder tumor antigen (BT A) stat, nuclear matrix protein 22 (NMP22), UroVysion and ImmunoCyt are considered established for the diagnosis of bladder cancer in those considered to be at very high risk and for the follow up of those with a history of bladder cancer. The use of other tumor markers, such as Cxbladder, is considered experimental / investigational as there is insufficient evidence on the diagnostic accuracy of these other markers. Therefore, we are not able to approve this request."

Petitioner's Argument

In her request for an external review, the Petitioner wrote:

I don't understand why my test was not covered. I was in severe pain. I was unable to urinate at times, and unable to make it to the bathroom at times. Just because they found nothing abnormal should not negate the fact I needed the test to determine that. I cannot afford to pay this!

In a letter of appeal to BCBSM dated March 9, 2016, the provider's representative explained the test:

I am writing to appeal your denial of coverage for the Cxbladder test for [the Petitioner]. The denial reason indicates that the Cxbladder™ test is considered Not medically necessary. . . .

The Cxbladder test is a non-invasive urine based-laboratory developed test (LDT) based on a bladder cancer molecular signature comprising the quantitative measurement of 5 mRNA biomarkers clinically associated with urothelial cancer: CDC2, HOXA 13, MDK, IGFBP5 and CXCR2. The five biomarkers are involved in varying aspects of cell growth, division, proliferation and

inflammation. Four markers show differential expression in cancers of the urinary tract and one marker is indicative of inflammatory conditions.

Cxbladder performance was validated in a prospective multicenter clinical study and published in the peer reviewed Journal of Urology. In this study Cxbladder had an overall sensitivity of 82% at a specificity of 85% with a NPV of 97% for the detection of urothelial cancer. Cxbladder exhibits high sensitivity and specificity, potentially replacing the need for cytology, other urine based laboratory tests, and double contrast CT scans in the clinical workup and increasing diagnostic confidence by combining the Cxbladder test with cystoscopy.

The Cxbladder test may be ordered on patients at an increased risk of bladder cancer to aid in the diagnosis of new or recurrent bladder cancer. Cxbladder can also be used in certain high-risk group patients who present with gross or micro hematuria as a quick and rapid test to detect potential urothelial cancer patients and rule out bladder cancer in patients with an increased risk of bladder cancer due to the test's NPV of 97.7%.

Director's Review

The certificate (p. 33) covers laboratory and pathology tests and services. However, the certificate (p. 142) excludes coverage for experimental treatment:

Services That Are Not Payable

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment ...

"Experimental treatment" is defined in the certificate (p. 160) as

[t]reatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as "investigational" or "experimental services."

To determine if the Cxbladder test was investigational for the treatment of the Petitioner's condition, the Director presented the question to an independent review organization (IRO) as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is board certified in urology and sleep medicine, is familiar with the medical management of patients with the Petitioner's condition, and has been in active practice for more than 15 years. The IRO report included the following analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that the Cxbladder lab and pathology testing (procedure code 81479) performed on 8/24/15 was experimental / investigational for diagnosis and treatment of the member's condition.

Rationale:

* * *

The MAXIMUS physician consultant indicated that the American Urological Association (AUA) guidelines for the evaluation of microscopic hematuria do not recommend the use of the Cxbladder test. The physician consultant explained that testing with Cxbladder is not likely to be more beneficial than cystoscopy in evaluation of microscopic hematuria. The consultant noted that urinary biomarker tests, such as Cxbladder, give significant false negative results in patients with bladder cancer and are subject to false positive results in others. The consultant also noted that the accuracy of this test is poor for low-stage and low-grade tumors. A meta-analysis that reviewed Ovid MEDLINE, Cochrane Central Register of Controlled Trials, Cochrane Database of Systemic Reviews and other sources demonstrated limited accuracy of the Cxbladder test.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the Cxbladder lab and pathology testing (procedure code 81479) performed on 8/24/15 was experimental / investigational for diagnosis and treatment of the member's condition. [References omitted]

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 extensive 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 why the IRO's recommendation should be rejected, finds the Cxbladder test is investigational for the Petitioner's condition and is therefore not a covered benefit.

V. ORDER

The Director upholds BCBSM's final adverse determination.

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 Michigan 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:



Randall S. Gregg
Special Deputy Director