STATE OF MICHIGAN

DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES

Before the Director of Insurance and Financial Services

In the matter of:

[redacted]

Petitioner,

v **File No. 154158-001**

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 18th day of August 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

[redacted] (Petitioner) was denied coverage for a laboratory test by his health plan, Blue Cross Blue Shield of Michigan (BCBSM).

On June 15, 2016, [redacted], the Petitioner's authorized representative, 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 material submitted, the Director accepted the request on June 22, 2016.

The Petitioner receives group health care benefits through a plan underwritten by BCBSM. 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 27, 2016.

Because the case involves medical issues, it was assigned to an independent review organization, which provided its analysis and recommendation to the Director on July 26, 2016.

II. Factual Background

The Petitioner's health care benefits are described in BCBSM's *Community Blue Group Benefits Certificate LG* (the certificate).

The Petitioner has recurrent bladder cancer. His urologist ordered Cxbladder, a urine-based test for the detection of bladder cancer. The test was performed on May 15, 2015; the charge was $2,995.00. BCBSM denied coverage for the test, saying it 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 17, 2016, affirming its denial. The Petitioner now seeks a review of that final adverse determination from the Director.

III. Issue

Is the Cxbladder test investigational when used in the medical management of the Petitioner's condition?

IV. Analysis

BCBSM's Argument

In its final adverse determination, BCBSM's representative explained the reasons for the denial:

> We denied payment for the laboratory service because the Cxbladder test is considered investigational ... After careful review, I confirmed the denial is appropriate and must be maintained. [The Petitioner's] health care Plan does not cover investigational or experimental services. Therefore, payment cannot be approved.
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> * * *
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> To ensure all consideration, an associate medical director, a board-certified D.O. in Internal Medicine, reviewed the appeal, [the Petitioner's] claim, and his health care plan benefits for BCBSM. Our consultant determined the following:
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>> According to the [BCBSM] medical policy, "Urinary Tumor Markers for Bladder Cancer," the assessment of urinary tumor markers using bladder tumor antigen (BTA) stat, nuclear matrix protein 22 (NMP22), UroVysion and ImmunoCyt are considered

> established for the diagnosis of bladder cancer in very high risk patients 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 evidenced on the diagnostic accuracy of these other markers. Therefore, we are not able to approve this request.
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> The BCBSM / Blue Care Network Joint Uniform Medical Policy Committee (JUMP) has determined that the service is investigational. . . .
>
> An investigational status means that the safety and effectiveness of a particular technology has not been definitively determined. An established technology means that the safety and effectiveness have been definitively determined. Investigational medical policies are reviewed regularly to guarantee that the investigational status continues to be supported by the evidence.
>
> Therefore, based on our medical consultant's determination that the service is considered investigational, together with the terms of [the Petitioner's] coverage stating experimental / investigational services are not payable, we must maintain our denial.

Petitioner's Argument

In a June 9, 2016, letter filed with the external review request, the Petitioner's authorized representative said:

> I am writing to appeal [the] denial of coverage for the Cxbladder test for [the Petitioner]. The denial reason indicates that the Cxbladder test is considered Experimental / Investigational. I disagree with this decision and I am outlining my reasons below. I would appreciate your prompt review of this information and authorization of coverage for the Cxbladder test for this patient.
>
> 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, MOK, 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.
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> * * *
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> **Patient Test Results:** Cxbladder aids in the detection and monitoring of Urothelial Carcinoma by indicating the relative risk of the patient having UC. The Cxbladder test results are definitive and actionable on each patient ...

Director's Review

The certificate (p. 35) covers diagnostic laboratory and pathology services. However, the certificate (p. 133) excludes coverage for experimental or investigational treatment or services. "Experimental treatment" is defined in the certificate (p. 150) 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."

The question of whether the Cxbladder test is investigational for the medical management of the Petitioner's condition was presented 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, published in peer review medical literature, and in active practice. The IRO report concluded that the Cxbladder test was experimental or investigational:

> **Review Question to Answer:**
>
> **Is the Cxbladder test performed on May 15, 2015 experimental / investigational for treatment of the enrollee's condition?**

> Yes. The Cxbladder test is experimental / investigational for the treatment of the enrollee's condition. It is still considered experimental, by virtue of the fact that it is not written as a gold standard or guideline standard of care in a pathway manuscript or textbook. It has been studied and compared to other therapies and has been deemed safe, but is not part of a universal protocol.

The IRO report went on to explain the conventional treatment for detecting bladder cancer:

> For a patient with the enrollee's clinical circumstance of recurrent bladder cancer, screening for recurrence is required. Cytology is universally accepted as well as computed tomography (CT) scan and cystoscopy. In some cases, one (1) modality may pick up recurrence of new malignancy while one (1) of the others does not, hence all three (3) are required in serial intervals. For this enrollee, CT plus cystoscopy and cytology would be required, and the best of these type of studies would provide the most advantage in picking up tumor presence.

The IRO report also noted that "the Food and Drug Administration (FDA) has not endorsed the Cxbladder test at this time." Based on foregoing, the Director concludes that the Cxbladder test is experimental or investigational and is therefore not a benefit under the terms of the certificate.

Notwithstanding its conclusion that the Cxbladder test is experimental or investigational, the IRO report went on to say that the Cxbladder test was "medically necessary for [the Petitioner]" and recommended that BCBSM's final adverse determination be overturned.

The Director is not required to accept a recommendation from an IRO. *Ross v Blue Care Network of Michigan,* 480 Mich 153 (2008). However, 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 Director rejects the IRO's recommendation that the test is medically necessary and should be covered.

The Director notes that the certificate (p. 133) says unequivocally, "We do not pay for experimental treatment" and the IRO report established that the test is experimental. Further, while the IRO report said the Cxbladder test compares favorably to certain diagnostic and screening modalities, it "is not written as a gold standard or guideline standard of care in a pathway manuscript or textbook," i.e., it "has not been

scientifically proven to be as . . . effective for treatment of the patient's conditions as conventional treatment."

The Director concludes that the Cxbladder test is experimental or investigational and is therefore not a covered benefit under the certificate.

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