

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. 150802-001

Blue Care Network of Michigan  
Respondent

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Issued and entered  
this 10<sup>th</sup> day of December 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On November 9, 2015, ██████████ authorized representative of ██████████ (Petitioner) filed a request with the Department of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives group health care benefits through a group plan underwritten by Blue Care Network of Michigan (BCN). The benefits are described in BCN's *BCN1 for Large Groups Certificate of Coverage*.

The Director notified BCN of the external review request and asked for the information used to make its final adverse determination. BCN furnished the information on November 10, 2015. On November 17, 2015, after a preliminary review of the information submitted, the Director determined the case was eligible for an external review.

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on December 1, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner, ██████ years old, has a history of T1c prostate cancer. His physician recommended a test – Oncotype DX Prostate Cancer Assay– to help determine the best course of treatment. The test was provided on November 7, 2014 at a cost of \$4,180.00.

BCN denied coverage for the test, ruling that it was investigational/experimental in the treatment of the Petitioner's condition. The Petitioner appealed the denial through BCN's internal grievance process. BCN issued a final adverse determination on September 29, 2015. The Petitioner now seeks review of that determination from the Director.

### III. ISSUE

Is the Oncotype DX prostate cancer test the Petitioner received experimental or investigational as part of the Petitioner's cancer treatment?

### IV. ANALYSIS

#### BCN's Argument

In its September 29, 2015 final adverse determination, BCN wrote:

Our step two grievance panel...reviewed your request for coverage of ODX prostate genetic testing, and upheld the previous denial.

They determined that Blue Care Network cannot authorize the service as the requested service is experimental/investigational. The denial is based on our medical policy titled, "Gene-Based Tests for Screening, Detection, and/or Management of Prostate Cancer." This enclosed policy states the effectiveness of this treatment has not been established to be equal to or better than traditional therapy.

Also, please reference the enclosed BCN 1 Certificate, section 9.4 titled "Non-Covered Services."

#### Petitioner's Argument

In support of BCN covering the test, representative of the lab that provides the test wrote:

With his recent diagnosis of prostate cancer, [Petitioner] was proposed a variety of options regarding how best to treat his cancer. His biopsy and PSA level indicated that he had low risk disease. These characteristics are helpful, but often are not reflective of the extent of the tumor within the prostate. Thus, a physician cannot fully determine whether a patient has low risk prostate cancer that can be managed with active surveillance (AS), a clinically acceptable course of conservative management for men with low risk cancers, or whether he has aggressive prostate cancer and would benefit from surgery or radiation therapy. Without the results of an Oncotype DX Prostate Cancer Assay, he and his physician did not have a complete understanding of the biology of his cancer.

\* \* \*

The Oncotype DX Prostate Cancer Assay...is a commercially available biopsy-based RT-PCR 17-gene assay, representing four important molecular pathways, that provides a biologic measure of cancer aggressiveness. The assay is indicated

for men who are considered candidates for AS....The Oncotype DX results are reported as a Genomic Prostate Score (GPS) that, when combined with other clinical factors, can further clarify risk. It has been designed to inform decisions between AS and immediate treatment. Two independent validation studies have demonstrated that the Oncotype DX Prostate Cancer Assay can predict the likelihood of high grade and/or non-organ confined disease, together defined as adverse pathology, in men presenting with low- or intermediate-risk features at biopsy.

In summary, physicians need better risk assessment tools to help identify men with prostate cancer who can be safely managed with AS versus those who need more aggressive treatment. Assessment of the patient's own tumor biology is key. Many physicians are now incorporating Oncotype DX Prostate Cancer testing into their practice. Based on this information, I request that you reconsider your denial and approve coverage of this test. It has provided [Petitioner] and his physician powerful and relevant information that is otherwise not available, and it has allowed him to have as much information possible to make an important treatment decision.

#### Director's Review

The Petitioner's health benefit plan excludes coverage for experimental and investigational medical services. See section 9.4 of the *BCN I* certificate of coverage.

To evaluate the question of whether the Oncotype DX prostate cancer test is investigational/experimental, 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 who is board certified in urology and has been in active practice for more than 18 years. The reviewer is familiar with the medical management of patients with the Petitioner's condition. The reviewer's report included the following analysis:

[T]here is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with the Oncotype DX Prostate Cancer Assay. The National Comprehensive Cancer Network (NCCN) updated guideline for prostate cancer discusses Prolaris and Oncotype DX as molecular markers and concluded that "Both molecular biomarker tests have been developed with extensive industry support, guidance, and involvement, and have been marked under the less rigorous FDA regulatory pathway for biomarkers. Their clinical utility awaits evaluation by prospective, randomized clinical trials, which are unlikely to be done. The marketplace and comparative effectiveness research may be the only means for these tests and others like them to gain their proper place for better risk stratification for men with clinically localized prostate cancer." (NCCN Clinical Practice Guidelines in Oncology...)

Pursuant to the information set forth above and available documentation...the Oncotype DX Prostate Cancer Assay performed on 11/7/14 was investigational for diagnosis and treatment of the member's condition. [References omitted.]

While the Director is not required in all instances to accept the IRO's recommendation, the recommendation is afforded deference by the Director. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). 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. See MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that the Oncotype DX test is investigational in the treatment of the Petitioner's condition. For that reason, the test is not a covered benefit.

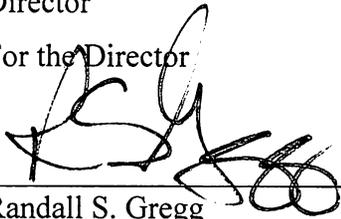
#### V. ORDER

BCN's final adverse determination of September 29, 2015 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



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Randall S. Gregg  
Special Deputy Director