

**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. 150101-001**

**Blue Care Network of Michigan**

**Respondent**

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**Issued and entered**  
**this 21<sup>st</sup> day of October 2015**  
**by Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

The Petitioner, ██████████, is appealing a denial of coverage for a medical test ordered by his physician as part of the Petitioner's treatment for prostate cancer. On September 29, 2015, ██████████, the Petitioner's authorized representative and an employee of the laboratory that performed the disputed test, filed a request for external review 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.* On October 6, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on October 20, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner receives health care benefits through a group plan underwritten by Blue Care Network of Michigan (BCN). The Petitioner's health care benefits are described in BCN's *BCN I* certificate of coverage.

The Petitioner's physician recommended the Oncotype DX Prostate Cancer Assay to help determine the best course of treatment. The test was processed on March 14, 2014 by Genomic Health, Inc., the laboratory that developed the test. The test cost \$3,820.00.

BCN denied coverage ruling that the test is experimental for treatment of the Petitioner's condition. The Petitioner appealed the denial through BCN's internal grievance process. BCN issued its final adverse determination on August 10, 2015, confirming the denial. The Petitioner now seeks review of that determination from the Director.

### III. ISSUE

Is the Oncotype Dx test experimental or unproven as part of the treatment of the Petitioner's prostate cancer?

### IV. ANALYSIS

#### BCN's Argument

In its final adverse determination, BCN stated:

[T]here is insufficient evidence in the peer reviewed literature to establish the analytic validity, clinical validity or clinical utility of the requested Oncotype DX Prostate Cancer Assay test. The request does not meet the requirements of the member's BCN [certificate of coverage] section 2.01 Unauthorized and Out of Plan Service, and 2.09 Research or Experimental Services.

#### Petitioner's Argument

In a letter dated September 22, 2015, submitted in support of BCN covering the test, a 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.

As you know, many newly diagnosed patients have prostate cancers that are indolent and slow growing and could managed effectively with AS, while others have aggressive cancers that require immediate intervention. Men and their physicians face a major decision – should the cancer be treated aggressively with radical prostatectomy or radiation, or is AS an appropriate alternative. The

clinical uncertainty in our ability to discriminate indolent disease from more aggressive cancer contributes to the widespread overtreatment of low risk prostate cancer. Over 30% of patients with low risk, indolent-appearing cancers on diagnostic biopsy are found to have high grade or high stage disease at time of surgery.

As such, patients who may be otherwise managed safely with AS often seek definitive treatment. These interventions are associated with significant comorbidities that impact the quality of life and increase healthcare costs. Use of this validated, fit-for-purpose gene expression assay can identify men who can be considered for AS by reflecting the underlying tumor biology, improving upon the existing clinical and pathologic metrics for risk stratification, and providing more confidence and certainty in the diagnosis men with clinically low risk prostate cancer.

\* \* \*

**Please note that the revised NCCN guidelines now recognizes tissue based molecular assays, and specifically describes the Oncotype DX assay, as an option to improve risk stratification for men with localized prostate cancer who have > 5 years of life expectancy.**

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. [References omitted.]

### Director's Review

The *BCN I* certificate contains this coverage exclusion in Section 2.09 Research or Experimental Services:

Benefits are not provided for care, services, supplies, devices, drugs, or procedures which are experimental, or research in nature unless specifically approved as a benefit by the Health Plan Board of Directors. Unusual procedures or services for which costs or risks are excessive and probable benefits are slight are not benefits except as determined by the Health Plan's Medical Director.

BCN maintains there is insufficient evidence in peer-reviewed literature to establish the analytic validity, clinical validity or clinical utility of the requested Oncotype DX Prostate Cancer Assay test, therefore, it is considered a research or experimental service.

To evaluate the question of whether the Oncotype DX prostate cancer test is experimental or investigational, 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 has been in active practice for more than 12 years, is certified by the American Board of Urology, and is published in peer reviewed medical literature. The IRO reviewer's report included the following analysis and recommendation:

The standard of care for a patient in this situation would be a discussion of active surveillance versus other more aggressive treatment options, such as prostate brachytherapy, external beam radiation, cryotherapy, or surgical removal. The current standard of care is not gene testing in this situation.

The Oncotype DX prostate cancer assay measures the expression of twelve (12) cancer-related genes from four (4) biological pathways and five (5) reference genes, which are algorithmically combined to calculate a Genomic Prostate Score. The accuracy of the Genomic Prostate Score derived from Oncotype DX in predicting the absence of aggressive features on tumor biopsy approaches 90%, compared with 80% using Gleason grade, clinical stage, and PSA. Currently, published evidence for this gene-based test is limited and the clinical utility has not been fully demonstrated.

In the most current American Urological Association (AUA) guideline for the management of clinically localized prostate cancer, there is no strong recommendation for gene-based prostate cancer testing. However, they do suggest that further testing and research is needed in this field. Although the Oncotype DX prostate cancer assay had been analytically validated, the clinical usefulness of the gene-based test is yet to be fully demonstrated. The Oncotype DX prostate cancer assay was United States Food and Drug Administration (FDA) approved in 2012.

The enrollee has a low grade, low stage, low volume prostate cancer with 1/12 cores of Gleason 3+3 at 6 in 5% of 1/12 cores. Based on the clinical documentation submitted for review and current standards of care in the field, the Genetic Oncotype DX prostate test was experimental/investigational for this enrollee at the time of testing.

**Recommendation:**

It is the recommendation of this reviewer that the denial issued by Blue Care Network of Michigan for the Oncotype DX Prostate Cancer Assay (CPT 84999) on March 14, 2014 be upheld. [References omitted.]

The Director is not required in all instances 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. 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 Prostate Cancer Assay test is, in this instance, experimental/investigational and, for that reason, is not a covered benefit.

#### V. ORDER

BCN's final adverse determination of August 10, 2015 is upheld. BCN is not required to provide coverage for the Petitioner's March 14, 2014 Oncotype DX Prostate Cancer Assay test.

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