

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. 149392-001

Blue Care Network of Michigan,

Respondent.

Issued and entered
this 29th day of September 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

[REDACTED] (Petitioner) was denied coverage for a laboratory test by his health insurance plan. On August 17, 2015, [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.* On August 24, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits under an individual plan through Blue Care Network of Michigan (BCN), a health maintenance organization. The Director immediately notified BCN of the external review request and asked for the information it used to make its final adverse determination.

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on September 2, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in BCN's *Certificate of Coverage for Individuals* (the certificate).

The Petitioner was diagnosed with prostate cancer following a September 14, 2014, biopsy. His physician recommended the Oncotype DX Prostate Cancer Assay to help determine the course of treatment. The test was performed on August 5, 2014; the charge was \$4,180.00.

BCN denied coverage for the test, saying that it was investigational in the treatment of Petitioner's condition. The Petitioner appealed the denial through BCN's internal grievance process. At the conclusion of the process, BCN initially issued a final adverse determination erroneously dated July 2, 2014,¹ affirming its denial. The Petitioner now seeks review of that final adverse determination from the Director.

III. ISSUE

Is the Oncotype DX Prostate Cancer Assay test investigational for treatment of the Petitioner's condition?

IV. ANALYSIS

Petitioner's Argument

In an August 12, 2015, letter submitted with the external review request, a representative of the laboratory that provided the test wrote:

. . . [The Petitioner] is a [REDACTED] year old patient, recently diagnosed with prostate cancer. His physician ordered the Oncotype DX® Prostate Cancer Assay to help guide risk assessment and determine the most appropriate treatment. [The] health plan denied coverage for this test due to Experimental/Investigational....

With his recent diagnosis of prostate cancer, [the 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 - i.e. those with NCCN very low-, low-, and a subset of intermediate risk prostate cancer. 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

¹ It should have been dated July 2, 2015.

Assay can predict the likelihood of high grade and/or non-organ confined disease, together defined as adverse pathology (AP), in men presenting with low- or intermediate-risk features at biopsy. In multivariable analysis, the GPS was found to predict AP at radical prostatectomy, after accounting for standard clinical and pathological risk factors (biopsy GS, clinical T-stage, baseline PSA, and age) and identified more patients with very low- and low-risk biological potential who could be considered as appropriate for AS management. In addition, the second validation study demonstrated that the Oncotype DX Prostate Cancer Assay has a significant association with risk of biochemical recurrence (BCR). Thus, the Oncotype DX Prostate Cancer Assay is combined with established clinical and pathological characteristics to provide a more precise assessment of tumor aggressiveness at the time of diagnosis to help guide individual treatment decisions. . . .

The GPS has shown strong clinical utility. The assay results enable physicians and patients to make personalized treatment decisions with more confidence at the time of diagnosis regarding their suitability for AS or the need for immediate treatment. Two clinical utility studies have shown the impact of GPS on treatment recommendations. Both studies demonstrated that use of the GPS increased the proportion of men for whom AS was recommended. In the prospective decision impact study of over 150 patients, patients who received GPS testing had a 24% relative increase in AS recommendations. In the chart review study of over 200 patients, when actual treatment received was captured, there was a 22% relative increase in post-assay AS recommendations. Actual use of AS increased 24% (absolute; relative increase 56%). All changes in treatment recommendation and/or treatment were directionally consistent with GPS results.

* * *

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. . . . It has provided [the 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.

BCN's Argument

In its final adverse determination, BCN gave its reasons for denying coverage of the Oncotype DX Prostate Cancer Assay:

The [grievance] Panel . . . reviewed the medical documentation you submitted, the BCBSM/BCN Gene Expression Profile Analysis for Prostate Cancer Management Medical Policy and the member's BCN Certificate of Coverage for Individuals and maintained the denial.

The Panel maintained the denial stating that per the Gene Expression Profile Analysis for Prostate Cancer Management Medical Policy the Oncotype DX Prostate Cancer Assay test

is considered investigational. Per the member's BCN Certificate of Coverage for Individuals section 9.4 Non-Covered Services: All facility, ancillary and physician services, including diagnostic tests, related to experimental or investigational procedures are not covered. Additionally, per section 9.1 Unauthorized and Out of Network Services: Except for emergency care as specified in Section 8, health, medical and Hospital services listed in this Certificate are covered only when provided by a BCN Participating Provider; and Preauthorized by BCN for select services. Pre-authorization was not requested for this test.

Director's Review

The certificate, in section 9.4, "Non-Covered Services" (pp. 58-59), has this exclusion regarding experimental and investigational services:

Coverage does not include the following services:

* * *

- All facility, ancillary and physician services, including diagnostic tests, related to experimental or investigational procedures.

The certificate (p. 56) defines an "experimental or investigational" service as

a service that has not been scientifically demonstrated to be as safe and effective for treatment of the Member's condition as conventional or standard treatment in the United States.

To answer the question of whether the Oncotype DX Prostate Cancer Assay was investigational, the Director presented the issue to an independent review organization (IRO) for analysis and a recommendation 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, has been in active practice for more than 18 years, and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis and recommendation:

The MAXIMUS physician consultant explained that there 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. [Citation omitted]"

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the Oncotype DX Prostate Cancer Assay performed on 8/5/14 was investigational for diagnosis and 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 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 in this case, finds that the Oncotype Dx Prostate Cancer Assay test is investigational for the treatment of the Petitioner's condition and therefore is not a covered benefit.²

V. ORDER

BCN's final adverse determination of July 2, 2015 is upheld. BCN is not required to provide coverage for the Petitioner's August 5, 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



Randall S. Gregg
Special Deputy Director

² In deciding the case on these grounds, the Director does not need to address BCN's alternative argument that the Petitioner did not obtain the required preauthorization for the test.