

**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. 153047-001**

**Blue Care Network of Michigan**  
**Respondent**

---

**Issued and entered**  
**this 3<sup>rd</sup> day of May 2016**  
**by Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On April 4, 2016, ██████████, 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 health care benefits through a group plan underwritten by Blue Care Network of Michigan (BCN), a health maintenance organization. The benefits are described in BCN's *Classic 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's response was received on April 5, 2016. After a preliminary review of the information submitted, the Director accepted the request on April 11, 2016.

The medical issues in the case were analyzed by an independent review organization which submitted its report to the Director on April 25, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner has cutaneous melanoma. Her physician ordered the DecisionDx-Melanoma assay, a test used to determine the risk of metastasization. The test was performed on August 14, 2015, by Castle Biosciences, Inc. which charged \$7,918.00. BCN denied coverage for the test, ruling that it was experimental/investigational in the treatment of the Petitioner's condition and was therefore not a covered benefit.

The Petitioner appealed the denial through BCN's internal grievance process. At the conclusion of that process BCN issued a final adverse determination dated February 11, 2016, affirming its denial. The Petitioner now seeks the Director's review of that final adverse determination.

### III. ISSUE

Was the DecisionDx-Melanoma test experimental/investigational for the treatment of the Petitioner's condition?

### IV. ANALYSIS

#### BCN's Argument

In its final adverse determination BCN wrote:

We based our decision on the fact that according to the Blue Care Network (BCN) medical policy Genetic Testing for Familial Cutaneous Malignant Melanoma, the procedure is considered experimental/investigational. The Blue Care Network, CBN Classic for Large Groups Certificate, section 9.4 Non-Covered Services, states that all facility, ancillary and physician services, including diagnostic tests, related to experimental or investigational procedures are not covered.

#### Petitioner's Argument

In a letter submitted with the request for external review, the Petitioner's authorized representative wrote:

The DecisionDx-Melanoma assay was ordered by Dr. [REDACTED], an in-network provider with your health plan, who deemed this testing medically necessary for your member based on intent to use the results in the management of the patient. The DecisionDx-Melanoma assay is...a validated prognostic assay for the prediction of metastatic recurrence in early stage Melanoma.

#### **Test Background:**

- Melanoma staging is characterized by the American Joint Committee on Cancer (AJCC) TNM system that defines cutaneous melanoma stages 0-IV. While the majority of clinical Stage I patients will be disease-free at 5 years, some Stage I patients will develop advanced disease. Furthermore, prognosis for clinical Stage II and III cases by TNM is highly variable, as evidenced by a 5-year survival rate of 53% to 82% for Stage II patients and a 5-year survival rate of 40% to 78% for Stage III patients. Although there have been considerable advancements in the staging of cutaneous melanoma (CM) in the last decade, including recognition of the prognostic value of ulceration status, mitotic rate, and sentinel lymph node status, molecular diagnostics offers an opportunity for further improvement. At present, sentinel lymph node biopsy

(SLNB) has been shown to be the most accurate independent prognostic parameter for patients with CM. Although the risk of recurrence for node-negative patients is significantly lower than for node-positive patients, the initial Multicenter Selective Lymphadenectomy Trial-1 (MSLT-1) analysis for intermediate-thickness melanomas observed that 2 of 3 patients who developed metastatic disease and ultimately died had a negative SLNB.

- By utilizing the intrinsic molecular biology within each patient's primary tumor, DecisionDx-Melanoma offers increased predictive accuracy over conventional population-based strategies by providing information on the probability of metastatic recurrence.
- The DecisionDx-Melanoma assay was developed to improve clinical outcomes by moving population based decisions to patient level decisions by identifying those Stage I and II melanoma patients who have a higher or lower risk of metastatic disease based on the individual genomic profile of the tumor biopsy. In particular, the test is intended for use by patients with thin tumors who are not eligible for SLNB according to the current guidelines, or those Stage I and II patients who received a SLN-negative outcome. Castle Biosciences has developed the DecisionDx-Melanoma assay, which is a prognostic gene expression profile assay that provides physicians and patients with an accurate prediction of risk for metastatic spread of melanoma. The test is performed on formalin-fixed paraffin-embedded (FFPE) tumor biopsies. It quantifies the mRNA expression of 28 prognostic genes in the tumor specimen and compares that gene expression signature to an established training set of melanomas with known outcomes using radial basis machine (RBM) predictive modeling, in order to classify a patient into one of two working groups: Class 1, assigned a low risk of metastasis at five years, or a Class 2, indicating a high risk of metastasis at five years.

**Clinical Validation, Overview of Evidence on Analytical Validity:**

The DecisionDx-Melanoma assay has been validated in two prospective multicenter independent clinical studies, which reported the ability of the test to accurately stratify low and high risk Stage I and II melanoma patients....

In a letter dated October 27, 2015, the Petitioner's physician, a plastic surgeon, wrote:

CLINICAL NEED: The AJCC diagnostic criteria are the current standard for staging cutaneous melanoma. However, histopathologic techniques alone (the elements of which comprise current staging), do not optimally identify patients at high risk for metastasis. For instance, while stage I melanomas are considered low risk as a group, some are actually at high risk for metastasis (Balch 2009). The challenge, of course, is identifying which ones. There is also poor accuracy for predicting those stage II patients at high risk for metastasis. Under the current staging system, the 5-year survival rate for clinical stage II patients is 53-82%, which overlaps significantly with the survival rates for stage III cases (Balch 2009; Balch 2010). Because staging drives prognostication and treatment planning, an objective molecular indication of tumor biology, such as

DecisionDx-Melanoma, for use in conjunction with traditional staging factors is very helpful in determining a *specific individual's* metastatic risk.

CLINICAL USE: The DecisionDx-Melanoma assay provides an objective, validated measure of tumor aggressiveness. The test results will be used in conjunction with other clinicpathologic assessments to provide improved support for a rational, *patient specific* treatment plan. Tumors which are Class 1 have a less aggressive phenotype and are associated with a low rate of metastasis within 5 years (2%), whereas a Class 2 phenotype is associated with a much higher rate of metastasis (73%) within 5 years. More aggressive management aimed at prophylaxis and/or early detection/intervention when mets [sic] occur could be considered for those patients identified as high risk. *Histopathology alone cannot distinguish between Class 1 and 2 phenotypes.* In conjunction with other clinical assessments, results from the DecisionDx-CM help identify an individual patient's risk profile, which aids in optimal treatment planning. This test is especially important for this patient given her very young age.

### Director's Review

BCN's *Classic for Large Groups* certificate of coverage excludes coverage for experimental/investigational medical care which it defines (on page 56) 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.

The question of whether the DecisionDx-Melanoma assay was experimental/investigational in the management of the Petitioner's condition was presented 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 physician reviewer is board certified in dermatology, has been in active practice for more than 10 years, and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis:

[T]here is not enough published data to support the routine use of the DecisionDx-Melanoma test currently....[T]his test is currently not the standard of care and is not recommended by the National Comprehensive Cancer Network Guidelines....[T]he available scientific evidence does not support that the DecisionDx-Melanoma test has a beneficial effect on health outcomes....[T]he use of this test would be considered experimental/investigational for thin melanomas, like this member's.

Pursuant to the information set forth above and available documentation...the DecisionDx-Melanoma test performed on 8/14/15 was experimental/investigational for diagnosis and treatment of the member's condition. (Saranga-Perry V, et al. Recent developments in the medical and surgical treatment of

melanoma. *CA: A Cancer Journal for Clinicians*. 2014 May/Jun;64(3):171-85.  
Gerami P, et al. Gene expression profiling for molecular staging of cutaneous melanoma in patients undergoing sentinel lymph node biopsy. *JAAD*. 72(5).

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 review 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)(1).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that the DecisionDx-Melanoma assay was experimental/investigational, and therefore is not a covered benefit.

#### V. ORDER

The Director upholds BCN's February 11, 2016 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