

**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. 152583-001**

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

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**Issued and entered**  
this 20<sup>th</sup> day of April 2016  
**by Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On March 28, 2016, ██████████ (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 issued 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 furnished the information on March 28, 2016. On April 5, 2016, 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 April 14, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner was diagnosed with lung cancer in April 2014. She underwent surgery followed by four cycles of chemotherapy. In March 2015, a recurrence of the disease was discovered. In April 2015, the Petitioner's physician ordered two tests relevant to this review: an epidermal growth factor receptor test (EGFR) and a blood test called VeriStrat. The EGFR test was performed by the St. Joseph Mercy Health System laboratory. The VeriStrat test was performed by Biodesix, a Boulder, Colorado

company that developed the test. BCN provided coverage for the EGFR test but denied coverage for the VeriStrat test, ruling that it was experimental/investigational.

The Petitioner appealed the denial of coverage through BCN's internal grievance process. BCN issued a final adverse determination on February 5, 2016 affirming its denial. The Petitioner now seeks the Director's review of that determination.

### III. ISSUE

Is the VeriStrat test experimental or investigational in the treatment of the Petitioner's condition?

### IV. ANALYSIS

#### BCN's Argument

In its final adverse determination, BCN wrote:

[T]he VeriStrat test performed is experimental/investigational and not covered per the BCBSM/BCN Medical Policy titled "Proteomic Testing for Targeted Therapy in Non-Small Cell Lung Cancer (NSCLC)" e.g. VeriStrat and as outlined in section 9.4 "Non Covered Services" of your certificate.

#### Petitioner's Argument

In a letter dated March 21, 2016, a representative of Bioesix wrote:

VeriStrat is a serum based proteomic test recommended by the National Comprehensive Cancer Network (NCCN) Guidelines for use in guiding treatment decisions in patients with advanced NSCLC [Non-Small Cell Lung Cancer] where EGFR mutation status is either wild-type or status unknown. According to the NCCN Guidelines, EGFR TKIs may be utilized in certain instances as an alternative to chemotherapy in the treatment of advanced NSCLC and may also serve as a maintenance therapy to help stall disease progression. VeriStrat provides clinically useful information for physicians at the time when these treatment decisions are being made.

...Proteomic testing is recommended in NCCN Guidelines for advanced NSCLC patients prior to treatment decisions being made by their physician. The test has been validated in multiple peer reviewed retrospective studies and a peer reviewed prospective, randomized Phase III trial (PROSE). VeriStrat provides information to clinicians and their patients with advanced NSCLC to help direct treatment options.

#### **VeriStrat Key Points:**

1. VeriStrat provides independent predictive and prognostic information to help guide treatment selection and avoid ineffective therapy by separating patients into two actionable groups....
2. VeriStrat is a blood-based proteomic test that does not require tissue or additional surgical biopsy....

3. VeriStrat is covered by Medicare....
4. NCCN Guidelines recommend proteomic testing to guide therapy for patients with advanced NSCLC and wild-type EGFR or with unknown EGFR status....
5. VeriStrat is proven to be both cost savings and cost effective in Health Economics study published in **Lung Cancer**....

Based on published clinical data, VeriStrat has been proven to be both a prognostic and predictive tool regarding the choice to treat with EGFR TKI therapy or single agent chemotherapy. VeriStrat has been evaluated in over 80 clinical studies encompassing over 5,000 advanced NSCLC patients, and in 2013 it became the first ever biomarker to have a successful, Phase III, prospective, clinical study completed in thoracic oncology. In the PROSE trial, the test was shown to have predictive and prognostic value in guiding treatment decisions for patients with advanced NSCLC....

VeriStrat has significant clinical utility and has proven to be a predictor of a patient's overall survival. The BR21 study published in Thoracic Oncology in 2012 demonstrated that patients with a test result of "VeriStrat Good" have a median survival nearly double that of patients with a test result of "VeriStrat Poor." To further assess the real world impact and clinical utility of VeriStrat, a study was performed and later published in Current Medical Research and Opinion in 2013. The study revealed that in 90% of cases the treatment decisions followed the VeriStrat test results, with 40% of physicians actually altering their treatment recommendation based on the VeriStrat test result.

#### Director's Review

BCN's *Classic for Large Group* certificate (pages v and 58) excludes coverage for services that are not medically necessary, including those determined to be experimental or investigational. BCN denied coverage for the VeriStrat test based on its medical policy titled, "Proteomic Testing for Targeted Therapy in Non-Small Cell Lung Cancer (NSCLC)" which states in part:

Mass spectrometry-based proteomic profiling to determine treatment for non-small-cell lung cancer (NSCLC) is experimental/investigational. There is insufficient evidence in medical literature to demonstrate that the use of this testing results in improved patient clinical outcomes.

To determine whether the VeriStrat test is experimental or investigational as part of the Petitioner's treatment, the Director requested that the issue be analyzed by 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 reviewer is a physician in active practice who is certified by the American Board of Internal Medicine with subspecialties in hematology and medical oncology. The reviewer is published in peer reviewed medical literature and is familiar with the medical management of patients with the Petitioner's condition. The reviewer's report included the following analysis and recommendation:

It is the determination of this reviewer that the proteomic testing for targeted therapy in non-small cell lung cancer is considered experimental/investigational and therefore was not medically necessary for treatment of the enrollee's condition.

**1. Is Proteomic Testing experimental or investigational?**

Yes, the proteomic testing is considered experimental/investigational. The research to assess the benefit of the VeriStrat test in patients with EGFR mutated lung cancer has not yet been done. Its use in EGFR mutated cancers is still experimental and investigative.

**2. Advise if the enrollee meets BCN's criteria.**

No, the enrollee does not meet BCN's criteria. The BCN criteria lists the VeriStrat test as experimental and investigative.

**3. Are BCN's criteria consistent with the standard of care?**

No, the BCN policy (Effective Date May 1, 2014) is not consistent with the literature and the current National Comprehensive Cancer Network (NCCN) guidelines. BCN Medical Policy states proteomic testing is experimental/ investigative with no mention of approval based on the specific EGFR status. NCCN guidelines support the use of proteomic testing only if the EGFR status of the tumor is wild type or unknown. This enrollee has a mutated EGFR and does not have wild type or unknown EGFR status.

**Clinical Rationale for the Decision:**

VeriStrat is a serum proteomic test which is designed to help identify patients who are likely to have good or poor outcomes after treatment with epidermal growth factor reception inhibitors (EGFRIs).

Several trials are noted in the clinical database regarding the VeriStrat proteomic test. One has been withdrawn. One is active but not recruiting. The two trials (#NCT02055144 and NCT022715581) that are still recruiting patients are not relevant to this case. Another trial (#NCT01652469) is a phase three trial that has been completed but the study results have not yet been published.

A phase three trial (NCT00989690) nicknamed PROSE, although listed as status unknown on the clinical trial database, was completed. The current NCCN guidelines refer to this trial and recommended the use of VeriStrat test as referenced by Biodesix Company in their appeal letter. However, the enrollee's condition does not qualify based on the tumor's EGFR status. The current version of the NCCN guidelines supports the use of the VeriStrat test in the management of non-small cell lung cancer if the EGFR status of the tumor is wild type or unknown. It is not recommended if the tumor has mutated EGFR. The tumor in this enrollee's case has EGFR mutations.

The physician ordered the EGFR mutation analysis and the VeriStrat test at the same time.

The VeriStrat test should have been considered after the EGFR status of the tumor had been determined. The company should also have requested the same and held off on doing the test until the EGFR status was known. Had the tumor been wild type (normal without mutations), then the VeriStrat test would have been appropriate.

The expert authors writing in the most recent edition of the online textbook UpToDate also recognize the results of this trial and state "a proteomic test (VeriStrat) has been developed to analyze serum using mass spectroscopy and separate patients into favorable and unfavorable groups. However, information from this type of testing does not currently influence our choices of therapy." Therefore, for the reasons noted above, the proteomic testing is experimental/ investigative and as such, was not medically necessary for the treatment of the enrollee'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 VeriStrat test is experimental/investigational in the treatment of the Petitioner's condition. Therefore, this test is not a covered benefit under the BCN *Classic for Large Groups* certificate of coverage.

**V. ORDER**

BCN's final adverse determination of February 5, 2016 is upheld. BCN is not required to provide coverage for the VeriStrat 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