

**STATE OF MICHIGAN**  
**DEPARTMENT OF ENERGY, LABOR & ECONOMIC GROWTH**  
**OFFICE OF FINANCIAL AND INSURANCE REGULATION**  
**Before the Commissioner of Financial and Insurance Regulation**

In the matter of

XXXXX

Petitioner

File No. 100784-001

v

Blue Cross Blue Shield of Michigan  
Respondent

---

**Issued and entered  
this 17th day of February 2009  
by Ken Ross  
Commissioner**

**ORDER**

**I  
PROCEDURAL BACKGROUND**

On October 14, 2008 XXXXX., authorized representative of XXXXX ("Petitioner"), filed a request for external review with the Commissioner of the Office of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Commissioner reviewed the material submitted and accepted the request on October 21, 2008.

Because it involved medical issues, the Commissioner assigned the case to an independent review organization which provided its analysis and recommendations to the Commissioner on November 4, 2008.

**II  
FACTUAL BACKGROUND**

The Petitioner receives health care benefits from Blue Cross Blue Shield of Michigan ("BCBSM") under its *Flexible Blue Group Benefit Certificate* ("the certificate"). The Petitioner is 45 years old and has been suffering from depression for nine years. She indicated that she has tried

numerous medications and ECT treatment in 2000 and 2001. The Petitioner's doctors have concluded that vagus nerve stimulation ("VNS") therapy is the best option to control her treatment-resistant depression.

The Petitioner requested authorization for VNS therapy. BCBSM denied the request indicating that VNS Therapy has not been scientifically demonstrated to be safe and effective for treatment of the Petitioner's condition and is therefore considered to be experimental.

Dr. XXXXX, the Petitioner's doctor, appealed the preauthorization denial through BCBSM's internal grievance process. After a managerial-level conference on February 20, 2008, BCBSM did not change its position and issued a final adverse determination on March 3, 2008. BCBSM treated this as a provider complaint and did not indicate that an external review could be requested and did not provide a copy of the Office of Financial & Insurance Regulation external review request form. Therefore, it was not until September 17, 2008, that the Commissioner's staff provided Dr. XXXX with a copy of the external review request form with directions to fill it out and have it signed by the Petitioner. Therefore, the October 14, 2008 request was timely and the Petitioner is entitled to an external review.

### **III ISSUE**

Did BCBSM properly deny preauthorization for the Petitioner's VNS Therapy?

### **IV ANALYSIS**

#### **Petitioner's Argument**

Dr. XXXX indicates that the Petitioner has tried more than thirty medications and other more drastic procedures such as electro-convulsive shock therapy to treat her depression. None of these treatments have been successful. Both Dr. XXXXX and the Petitioner's neurologist believe that VNS therapy is the best option to treat her treatment-resistant depression.

VNS therapy is approved by the FDA for treatment of treatment-resistant depression.

Therefore, her doctor believes that this care is medically necessary and not investigational or experimental for treatment of the Petitioner's condition. He argues that this care is a covered benefit under the certificate and BCBSM is required to pay for it.

#### BCBSM's Argument

Under the terms of the certificate of coverage, BCBSM does not pay for experimental treatment or services related to experimental treatment. BCBSM's medical consultant reviewed the documentation and concluded that VNS therapy for treatment of treatment-resistant depression is not supported by current studies and therefore should be considered experimental. BCBSM also referred to its medical policy for *Vagal Nerve Stimulation for Treatment-Resistant Depression* which states:

Vagal nerve stimulation is considered investigational for the treatment of treatment-resistant depression. The long-term safety and effectiveness of this procedure for treatment-resistant depression has not been proven.

BCBSM believes that it was correct in not authorizing the VNS treatment.

#### Commissioner's Review

The Petitioner's certificate sets forth the benefits that are covered. The sections of the certificate relevant to this appeal are reprinted below. In *Section 6: General Conditions of Your Contract* (page 6.3) the certificate states:

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment. . . .

Experimental treatment is defined in the certificate (page 7.8) as:

Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment.

Whether VNS therapy is experimental for treatment of the Petitioner's condition was presented by the Commissioner to an independent review organization ("IRO") for analysis as required by the Patient's Right to Independent Review Act. The IRO reviewer is a physician in

active practice certified by the American Board of Psychiatry and Neurology in the specialty of psychiatry and is a clinical assistant professor at a university-based school of medicine in its department of psychiatry.

The IRO reviewer indicated:

Unfortunately medical records were not submitted for review; and the details related to this patient are sketchy. The documentation submitted indicates that the patient has had multiple prior treatments but the details of past treatment in terms of the medications used, length of the trials, dosing, degree of compliance, adverse effects and response are not noted.

In the peer reviewed literature, the only double blind placebo controlled study regarding this modality failed to demonstrate a significant treatment effect. Subsequent studies have been flawed by lack of randomization and inadequate controls.

The American Psychiatric Association (APA) treatment guidelines indicate that there is inadequate data supporting its efficacy to warrant its use in standard psychiatric practice.

The Food and Drug Administration (FDA) has approved its use in patients who have failed to show adequate response to four or more adequate antidepressant treatments. However, this approval is contingent on additional studies being conducted regarding efficacy, dosing and patient selection.

Based on this analysis, the IRO reviewer concluded that the VNS therapy system is considered experimental and investigational for treatment of the Petitioner.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner; in a decision to uphold or reverse an adverse determination the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason why the recommendation should be rejected in the present case.

The Commissioner accepts the conclusion of the IRO and finds that the Petitioner's

proposed VNS therapy is experimental and investigational.

**V  
ORDER**

Respondent BCBSM's March 3, 2008 final adverse determination is upheld. BCBSM is not required to pre-authorize or cover the Petitioner's VNS Therapy.

Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.