

**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

v

File No. 109830-001

Blue Cross Blue Shield of Michigan  
Respondent

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Issued and entered  
this 5th day of January 2011  
by Ken Ross  
Commissioner

**ORDER**

**I**

**PROCEDURAL BACKGROUND**

On February 5, 2010, XXXXX, MD, authorized representative of XXXXX (Petitioner), filed a request for external review with the Commissioner 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 February 16, 2010.

The Commissioner immediately notified Blue Cross Blue Shield of Michigan (BCBSM) of the external review and requested the information it used in making its adverse determination.

The Commissioner assigned the case to an independent review organization (IRO) because it involved medical issues. The IRO provided its analysis and recommendations to the Commissioner on March 4, 2010.

**II**

**FACTUAL BACKGROUND**

The Petitioner receives group health care benefits as an employee of XXXXX, a BCBSM-

underwritten account. The terms of her coverage are found in the Community Blue Group Benefits Certificate (certificate).

On August 11, 2008, the Petitioner underwent surgery to insert an X-STOP spacer. The X-STOP spacer is a metal implant designed to fit between the spinous processes of the vertebrae in the lower back and relieve symptoms of spinal stenosis. BCBSM denied coverage for the surgery on the basis that the procedure is experimental and therefore not a benefit under the certificate.

The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM held a managerial-level conference on December 8, 2008, and issued a final adverse determination dated December 15, 2009, upholding its position.

### **III ISSUE**

Did BCBSM properly deny coverage for the Petitioner's X-STOP procedure?

### **IV ANALYSIS**

#### Petitioner's Argument

The Petitioner says she tried without success several methods of alleviating the back pain caused by her degenerative lumbar spondylolisthesis. In a January 28, 2010, letter, the Petitioner explained why she decided to have the X-STOP procedure:

In 2008 with my spinal stenosis becoming severe it was no easy decision to have surgery. I had tried a chiropractor, physical therapy, traction and epidural steroid injections, acupuncture & pain medications. My physical & emotional well being and my inability to perform my job as a mental health community based tech were challenged. Dr. XXXXX . . . and I felt surgery was very much needed at this time. . . .This was a less invasive, less expensive surgery.

The Petitioner's surgeon, Dr. XXXXX, wrote on September 16, 2009, in support of Petitioner's position:

I am asking that BCBS reconsider this decision and allow coverage (\$2898.03) for . . . X-STOP . . . surgery, . . . based on prior authorization of surgery, . . . medical necessity of the patient, and efficacy of the implant.

\* \* \*

The X-STOP IDP System is indicated for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis. . . . The X-STOP implantation procedure is a much less invasive procedure than other surgical decompressive procedures such as a laminectomy, and can often be performed under local anesthesia. The procedure preserves local anatomy so that, should device removal become necessary, additional surgical options are not precluded. **The X-STOP was approved by the FDA on November 21, 2005 and is a covered procedure per Medicare.**

\* \* \*

It is my professional opinion that the X-STOP IDP System was warranted, appropriate, and medically necessary for [the Petitioner].

The Petitioner believes the X-STOP procedure was medically necessary and appropriate, and is a covered benefit under the certificate.

#### BCBSM's Argument

BCBSM says that in the certificate under "Section 6: General Conditions of Your Contract," experimental services are excluded from coverage:

##### **Experimental Treatment**

##### **Services That Are Not Payable**

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment. . . . In addition, we do not pay for administrative costs related to experimental treatment or for research management.

In Section 7, "experimental treatment" is defined as:

Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as "investigational" or "experimental services."

BCBSM also relied on its medical policy title, "Interspinous Distraction Systems," for its decision to deny coverage. The policy says:

One implant indicated for treatment of intermittent neurogenic claudication that has received approval from the Food and Drug Administration (FDA) is the X-STOP Interspinous Process Decompression (IPD) System. This system was developed for patients over the age of 50 who have a confirmed diagnosis of neurogenic intermittent claudication and spinal stenosis, with symptoms aggravated by spinal extension and relieved by spinal flexion. The patients must have failed to respond adequately to six or more months of nonoperative treatment.

The North American Spine Society published guidelines in 2007 on the diagnosis and treatment of degenerative lumbar spinal stenosis. The conclusion was that there is insufficient evidence that placement of the X-STOP is more effective than medical/interventional treatment. Recommendations included performing a large, multicenter, three-arm randomized, controlled trial using a well-defined group of patients with moderate stenosis, comparing the use of X STOP to a microlaminotomy decompression and a well-defined medical/interventional treatment program.

\* \* \*

There have been some promising studies with noted improvement when IPD systems are used, but several questions remain about the device and additional studies need to be completed. Therefore, the interspinous distraction system implant is considered experimental/investigational.

BCBSM submits that its denial of the Petitioner's X-STOP procedure as experimental was correct and in accordance with the certificate.

#### Commissioner's Review

Dr. XXXXX, the Petitioner's surgeon and authorized representative for this external review, maintains that BCBSM authorized the X-STOP surgery in advance. He provided a number (T08415433) but did not furnish any documentation of prior authorization.

BCBSM says the number Dr. XXXXX refers to is for pre-notification, not pre-authorization.

According to BCBSM, pre-notification:

is used for hospitals to report early inpatient admission information to BCBSM, including subscriber, patient and facility demographic info and patient clinical information. This identifies patients who may be candidates for referral to case management, disease management or other care programs.

BCBSM says, "There was no Pre-authorization done for this surgical procedure."

There is no information in the record from which the Commissioner could conclude that X-STOP surgery was authorized in advance by BCBSM. Whether prior authorization was granted or not, the Commissioner notes this provision in Section 4 of the certificate ("Coverage for Physician and Other Professional Provider Services") that may relate to the Petitioner's obligation:

#### **HOW PHYSICIAN AND OTHER PROFESSIONAL PROVIDER SERVICES ARE PAID**

##### **Panel Providers**

\* \* \*

Panel M.D.s, D.O.s . . . may bill you for services not covered by your certificate. However, if the service is not covered because BCBSM determined that it was medically unnecessary or experimental, the provider may bill you only if:

- You acknowledge in writing before you receive the service that we will not cover it because it is medically unnecessary or experimental and you agree to receive the service and pay for it, and
- The provider gives you an estimate of what the services will cost you.

\* \* \*

Participating providers may **not** bill you for:

- Services that are not covered because BCBSM determined that the provider lacked the appropriate credentials or privileges needed to perform the services, or the provider failed to comply with BCBSM policies when rendering the services.

The question of whether the Petitioner's X-STOP procedure is experimental for treatment of his 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 reviewer is a physician certified by the American Board of Neurological Surgery; a fellow of the American College of Surgeons; an associate professor of surgery (division of neurosurgery) at a university-based school of medicine; is published in peer-reviewed literature; and is in active practice.

The IRO report summarized the present state of research and evaluation of the X-STOP procedure and then offered the following conclusion and analysis:

It is the determination of this reviewer that the X-STOP procedure is considered experimental for [the Petitioner's] condition.

**Clinical Rationale for the Decision:**

No long term outcome studies for the use of implanted interspinous process decompression systems have been completed to date. Numerous current prospective and retrospective studies with follow-up at one (1) to two (2) years have been reported.... The short-term data is promising for the device. The current US literature is lacking with most of the peer review literature being European in origin. The difficulty in comparing the outcome and efficacy of the device is based more upon the paucity of good comparison studies with regard to lumbar surgery.

\* \* \*

X-STOP decompression may at least be comparable to outcomes reported

in the literature for decompressive laminectomy. Due to flaws in studies on decompressive treatments, no definitive conclusions can be drawn.

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 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 IRO reviewer's conclusion and finds that the X-STOP procedure is experimental for treatment of the Petitioner's condition and is therefore not a covered benefit under the terms of the certificate.

Finally, the Commissioner notes that Petitioner's surgeon is prohibited under his BCBSM provider agreement from billing a BCBSM member for any procedure deemed experimental unless the surgeon has prior written acknowledgment from the member that the member is aware the procedure is not covered by BCBSM and that the member nevertheless wishes to proceed with the treatment.

## **V ORDER**

Respondent BCBSM's December 15, 2009, final adverse determination is upheld. BCBSM is not required to authorize coverage for the Petitioner's X-STOP surgery.

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.