

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX

Petitioner

v

File No. 117757-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 9th day of May 2011
by R. Kevin Clinton
Commissioner

ORDER

I

PROCEDURAL BACKGROUND

On October 26, 2010, 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 November 3, 2010.

Because it involved medical issues, the case was assigned to an independent review organization which provided its analysis and recommendation to the Commissioner on November 17, 2010.

II

FACTUAL BACKGROUND

The Petitioner receives health care benefits under BCBSM's *Group Conversion Comprehensive Health Care Benefits Certificate*.

The Petitioner, who is 24 years old, has a history of degenerative disc disease. She requested coverage for artificial intervertebral disc replacement surgery. BCBSM denied

authorization, asserting that the requested procedure is experimental or investigational and was therefore not a covered benefit.

The Petitioner appealed the denial through BCBSM's internal grievance process but BCBSM did not change its decision and issued a final adverse determination dated September 24, 2010.

III ISSUE

Did BCBSM properly deny authorization for the Petitioner's artificial intervertebral disc replacement surgery?

IV ANALYSIS

Petitioner's Argument

The Petitioner states that it is her surgeon's opinion that the best operation for her is the lumbar artificial disc replacement surgery, given her age and active lifestyle. The alternative, lumbar fusion, carries with it a significant incidence of the development of adjacent level disease as an individual grows older and it also stiffens the spine making it much more difficult to maintain an active lifestyle.

The Petitioner also states that other Board-certified neurologists believe that this procedure is not experimental based on medical literature that has been available since 2006. It is an FDA approved medical device, which reduces pain and preserves range of motion in the lumbar spine.

The Petitioner believes that her proposed surgery is not experimental, is medically necessary, and should be covered under her certificate.

BCBSM's Argument

BCBSM says that experimental or investigational services are not covered under the certificate which defines experimental treatment 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 says that its medical director is responsible for determining whether the use of any service is experimental based on medical criteria and guidelines. In the Petitioner's case it was determined that artificial intervertebral disc replacement is experimental because it has not been scientifically demonstrated to be better than currently available fusion procedures.

BCBSM believes that it is not required to provide coverage for the Petitioner's artificial intervertebral disc replacement surgery.

Commissioner's Review

The question of whether artificial disc replacement surgery is experimental for treatment of 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, who is familiar with the medical management of patients with the Petitioner's condition, is board certified in orthopedic surgery, holds an academic appointment at a major medical center and has been in practice for more than 18 years. The IRO reviewer, having examined the documents and arguments presented by the parties in this appeal, reached the following conclusion:

[A] total disc replacement using the ProDisc-L artificial disc is experimental/investigational for treatment of the member's condition.

* * *

[T]here are no long-term outcome studies demonstrating the safety and efficacy of artificial disc replacement. . . . [T]he long-term complications of artificial disc replacement are not well established. . . . [F]urther study is needed to demonstrate that lumbar artificial disc replacement is safe and effective for treatment of the member's condition. (Van Ooij. Complications of artificial disc replacement. *J Spine Disord.* 2003 Aug; 16(4):369-83.)

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.

Therefore, the Commissioner accepts the IRO reviewer's conclusion and finds that artificial intervertebral disc replacement surgery is experimental or investigational for treatment of the Petitioner's condition and is therefore not a covered benefit under the terms of the certificate.

**V
ORDER**

Respondent BCBSM's September 24, 2010, final adverse determination is upheld. BCBSM is not required to authorize coverage for the Petitioner's artificial intervertebral disc replacement 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.

R. Kevin Clinton
Commissioner