

**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**

**XXXXXX**

**Petitioner**

**v**

**File No. 119930-001**

**Blue Cross Blue Shield of Michigan**

**Respondent**

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**Issued and entered**  
**this 26th day of August 2011**  
**by R. Kevin Clinton**  
**Commissioner**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On March 8, 2011, XXXXXX (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 request and accepted it on March 15, 2011.

The Petitioner receives health care benefits under the BCBSM *Community Blue Group Benefits Certificate* (the certificate). Because medical issues were involved in this case, the Commissioner assigned the case to an independent medical review organization which provided its analysis and recommendation to the Commissioner on March 29, 2011.

**II. FACTUAL BACKGROUND**

The Petitioner's doctor requested authorization for a reconstruction spinal procedure known as the ProDisc-L Artificial Disc Replacement. BCBSM denied authorization indicating this procedure is experimental.

The Petitioner appealed BCBSM's denial of coverage through its internal grievance process. BCBSM held a managerial-level conference and issued a final adverse determination on January 24, 2011, affirming its position.

### III. ISSUE

Did BCBSM correctly deny coverage for the Petitioner's artificial disc replacement surgery?

### IV. ANALYSIS

#### Petitioner's Argument

The Petitioner argues that the requested procedure is not experimental and has been performed in Europe for 30 years. In addition, it was approved by the FDA for use in the United States in 2006. He does not know how a 30 year-old procedure that is FDA approved can be classified as experimental.

The Petitioner provided BCBSM several studies showing the short and long-term efficacy of total disc arthroplasty, but he states they have chosen to ignore these facts. The Petitioner believes that this care is medically necessary, not experimental and a covered benefit under his certificate of coverage with BCBSM. He wants BCBSM to pre-approve and pay for this care.

#### BCBSM's Argument

BCBSM states that under the terms of the certificate of coverage experimental or investigational services are not covered. The certificate states in "Section 6: General Conditions of Your Contract:"

##### **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 Section 7, the certificate 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. . . ."

BCBSM indicates its medical director is responsible for determining whether any service is experimental or investigational based on medical criteria and guidelines. BCBSM's medical director has determined that artificial intervertebral disc replacement has not been proven to be as safe and effective for treatment of the Petitioner's conditions as conventional treatment.

BCBSM believes that in the Petitioner's case it was determined that artificial intervertebral disc replacement is experimental. It has not been scientifically demonstrated to be better than currently available lumbar fusion procedures. Therefore, BCBSM did not authorize payment for

this care.

### Commissioner's Review

The question of whether total disc arthroplasty is experimental or investigational in the treatment of Petitioner's condition was presented to an independent review organization (IRO) for analysis as required by Section 11(6) of Patient's Right to Independent Review Act. The IRO reviewer is board certified in orthopedic surgery and holds an academic appointment. The reviewer has been in active practice for more than 18 years and is familiar with the medical management of patients with the Petitioner's condition. The IRO report includes the following comments:

[T]he long term outcomes and complications from total disc arthroplasty have not been established by clinical trials at this time. (van Ooji A, et al. Complications of artificial disc replacement: a report of 27 patients with the SB Charite disc. *J Spinal Disord Tech.* 2003 Aug; 16(4):369-83. Guyer RD, et al. Lumbar spinal arthroplasty: analysis of one center's twenty best and twenty worst clinical outcomes. *Spine.* 2008 Nov;33(23):2566-9. Punt IM, et al. Complications and reoperations of the SB Charite lumbar disc prosthesis: experienced in 75 patients. *Eur Spine J* 2008 Jan; 17(1):36-43.) . . . [T]he information provided for review demonstrates that the requested surgery would involve replacement of 3 disks. . . . [T]here is no data to support the use of 3 level disc replacement. . . . [T]he risks, complications and long term outcomes of 3 level disc replacement have not been established.

The reviewer concluded that the requested total disc arthroplasty is experimental for treatment of the Petitioner's condition.

While the Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference. 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 that judgment should be rejected in the present case.

The Commissioner accepts the conclusion of the IRO and finds that BCBSM's denial of coverage for total disc arthroplasty is consistent with the terms of the certificate. The Commissioner finds that BCBSM correctly processed Petitioner's request for coverage.

### **V. ORDER**

BCBSM's final adverse determination of January 24, 2011, is upheld. BCBSM is not required to provide coverage for the Petitioner's requested surgery.

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 Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

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R. Kevin Clinton  
Commissioner