

STATE OF MICHIGAN
DEPARTMENT OF CONSUMER & INDUSTRY SERVICES
OFFICE OF FINANCIAL AND INSURANCE SERVICES
Before the Commissioner of Financial and Insurance Services

In the matter of

XXXXX

Petitioner

File No. 87062-001

v

Blue Care Network of Michigan
Respondent

Issued and entered
This 8th day of February 2008
by Ken Ross
Acting Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On January 7, 2008, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Services under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq.* On January 14, 2008, after a preliminary review of the material submitted, the Commissioner accepted the request.

The case required analysis by a medical professional. Therefore, the Commissioner assigned the matter to an independent review organization (IRO) which submitted its recommendation on January 30, 2008.

II
FACTUAL BACKGROUND

The Petitioner is a member of Blue Care Network of Michigan (BCN). He has a history of degenerative disc disease with chronic pain. Through his orthopedic surgeon, XXXXX, MD, he requested authorization and coverage for total disc replacement surgery using a Charité™ artificial disc. The Charité is a three-piece articulating medical device consisting of a sliding

core sandwiched between two metal endplates. The endplates support the core and have small teeth which secure them to the vertebrae above and below the disc space. The sliding core fits in between.

BCN denied coverage for the surgery saying it is investigational. The Petitioner completed BCN's internal grievance process and received its final adverse determination letter dated October 4, 2007.¹

III ISSUE

Did BCN properly deny the Petitioner coverage for the Charité artificial disc procedure as investigational under the terms of its certificate?

IV ANALYSIS

Petitioner's Argument

The Petitioner has been through chiropractic treatment, narcotic analgesics, electrical stimulation, and numerous therapies (physical therapy, home exercise, aquatic therapy) to deal with his degenerative disc disease. He has also used many medications to keep him mobile. The side effects from the pills and injections include weight gain and bruising at the injection sites.

Because of the pain in his back and right leg, he is unable to perform activities of daily living and can no longer engage in activities with his children, like watching a whole game or using his boat to take them fishing. He is physically disabled as a result of his condition, which has put a strain on his family's income.

The Petitioner's orthopedic surgeon recommends he have a complete disc replacement at L-4 and L-5, rather than a 3 level fusion, because of his age and to improve his mobility. The

¹ Even though it appears at first glance that the Petitioner's request for external review may have been received by the Office of Financial & Insurance Services (OFIS) beyond the 60-day filing deadline in Section 11 of PRIRA (MCL 550.1911), the request was accepted because BCN acknowledged that the Petitioner did not immediately receive its final adverse determination.

Petitioner wants the Charité disc replacement surgery rather than spinal fusion because he feels it has a greater success rate and will result in more mobility.

Dr. XXXXX, in a letter dated February 14, 2007, requested coverage for the Charité surgery:

I am requesting medical review and authorization for payment on the [Petitioner]. The reason for review is: The procedure was billed with an unlisted spine procedure code: 22899, but new for 2007 has a procedure code of 22857. [The Petitioner] is a 42-year old who presents with a history of degenerative disc disease (DDD) and severe back pain. The [Petitioner's] symptoms have been unresponsive to palliative interventions, including physical therapy, pain medication, bed rest, analgesics and pain clinic treatments. Pain has affected [his] overall physical function, the ability to perform activities of daily living, and quality of life.

The AMA's CPT Editorial Panel has not established CPT codes that specifically identify the Charité surgical procedure. Until they do, I will be submitting the unlisted code of 22899 for the primary procedure. The secondary procedure will be submitted using CPT Code 22851, representing application of a biochemical device, namely the Charité artificial disc. I will be submitting a charge of \$18,000.00, which represents the value units of time, skill and overhead necessary to perform an arthroplasty with total discectomy, preparation of the interbody space and insertion of the Charité artificial disc.

* * *

In light of this clinical information, the [Petitioner's] condition and the anticipated outcomes, the use of the Charité disc is medically necessary and warrants coverage and reimbursement.

The Petitioner believes that BCN should provide coverage for the medically necessary procedure because it will relieve his pain and allow him to live a more normal and productive life.

BCN's Argument

In its final adverse determination, BCN denied coverage for the Charité artificial disc placement saying that the test is investigational. In "Part 2: Exclusions and Limitations," the Petitioner's certificate of coverage (the contract that defines his health care benefits) provides (page 17):

2.10 Research or Experimental Services

We do not pay for services, treatment or drugs (collectively referred to as “services”) that are experimental or investigational. All facility, ancillary and physician service, including diagnostic tests, which are related to experimental or investigational procedure, are not payable.

Definitions:

* * *

Experimental or Investigational

A service which has not been scientifically demonstrated to be as safe and effective for treatment of the patient’s condition as conventional or standard treatment.

* * *

EXPERIMENTAL OR INVESTIGATIONAL SERVICES

The BCN Medical Director is responsible for determining whether the use of any service is experimental or investigational. The service may be determined to be experimental or investigational when:

- A written study protocol, clinical trial or plan indicates the service or treatment is experimental or investigational;
- The service is delivered as part of or in the context of a clinical trial;
- The service is delivered pursuant to oversight by an institutional review committee or human subjects (or comparable) committee;
- The service has not received approval by the appropriate regulatory body, if applicable;
- There is no evidence that, at the time administered, the service is generally accepted by the medical community; or
- A written informed consent is used by the treating provider which refers to the services as experimental, investigational or other than conventional or standard therapy.

BCN’s medical policy title “Artificial Intervertebral Disc” says:

There is inadequate long-term data regarding the Charité artificial disc compared to lumbar fusion and inadequate data demonstrating whether maintenance of vertebral range of motion associated with the artificial disc results in improved outcomes. Indeed, there are disturbing reports of complications involving anterior migration of the prosthesis (with compression of the iliac vessels in one case), polyethylene wear, and subsidence of the prosthesis. Degeneration of other lumbar discs, facet joint arthrosis caused other problems.

BCN says the Charité surgical procedure is investigational at this time and therefore excluded under the terms of the Petitioner's coverage.

Commissioner's Review

Because this case involved medical issues, the Commissioner assigned it to an IRO for the recommendation of an expert. The IRO reviewer is a physician in active practice that is certified in orthopedic surgery, holds an academic appointment, and is familiar with the medical management of patients with the Petitioner's condition. The IRO report said:

The MAXIMUS physician consultant explained that artificial disc replacement is still experimental/investigational for treatment of multilevel lumbar disc degeneration. The MAXIMUS physician consultant also explained that more long term outcome data from clinical trials is needed to evaluate the safety and efficacy of artificial disc replacement. The MAXIMUS physician consultant indicated that the long-term complications from artificial disc replacement are not known at this time.

...[T]he MAXIMUS physician consultant determined that the requested artificial disc is experimental/investigational for treatment of the [Petitioner's] condition.

The IRO expert's recommendation, based on extensive expertise and professional judgment, is afforded deference by the Commissioner. The Commissioner can discern no reason why the IRO expert's judgment should be rejected in the present case. Therefore, the Commissioner accepts the IRO expert's conclusion that the Charite' artificial disc replacement is investigational at this time and therefore finds it is not a covered benefit under the Petitioner's health plan.

The Commissioner finds that BCN's final adverse determination is consistent with the terms of the certificate of coverage.

V ORDER

The Commissioner upholds BCN's October 4, 2007, final adverse determination denying authorization and coverage for Charite' artificial disc replacement in the Petitioner's case.

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 sixty 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 the Office of Financial and Insurance Services, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.