

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
BEFORE THE COMMISSIONER OF FINANCIAL AND INSURANCE REGULATION

XXXXX

Petitioner

v

File No. 120391-001

Priority Health

Respondent

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

ORDER

I

PROCEDURAL BACKGROUND

On April 4, 2011, 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 information and accepted the request on April 11, 2011.

The Commissioner notified Priority Health of the external review and requested the information it used in making its adverse determination. Priority Health submitted information on April 6 and April 18, 2011.

The case involves medical issues so the matter was assigned to an independent review organization, which submitted its recommendation on April 25, 2011.

II

FACTUAL BACKGROUND

The Petitioner is a member of Priority Health, a health maintenance organization. His group health care benefits are defined in the HMO Certificate of Coverage (the certificate).

The Petitioner has a history of chronic back pain and degenerative disc disease at L4-5 and L5-S1. He suffers from radiculopathy, a condition caused by compression of a nerve in the spine.

On November 16, 2010, the Petitioner's physician submitted a request to Priority Health for authorization for two-level artificial disc replacement surgery at a facility in XXXXX. The facility is not part of Priority Health's network of providers.

Priority Health denied the request, saying that medically appropriate treatment is available from network providers and that the proposed procedure is excluded from coverage because it is experimental or investigational.

The Petitioner appealed the denial through Priority Health's internal grievance process and received its final adverse determination dated February 15, 2011.

III ISSUE

Did Priority Health properly deny coverage for Petitioner's requested surgery?

IV ANALYSIS

Petitioner's Argument

The Petitioner says he did extensive research and concluded that multi-level lumbar artificial disc replacement is the standard of care for him. He says the benefit of artificial disc replacement over fusion surgery is that artificial disc replacement is reconstructive.

The Petitioner says that with this surgery, the spine regains its normal disc height which allows the spine to have its natural mobility and function. The artificial discs replicate the anatomic and biomechanical attributes of natural intervertebral discs. He says fusion surgery would limit the natural mobility and function of the spine.

The Petitioner believes the surgery is medically necessary and will allow him to resume a normal, active lifestyle with his family. He wants Priority Health to provide coverage for it.

Respondent's Argument

In its February 15, 2011, final adverse determination, Priority Health denied coverage for the two-level artificial lumbar disc replacement surgery because:

- o Medically appropriate treatment is available within the Priority Health network of providers and
- o Artificial lumbar disc replacement surgery is considered experimental and investigational and is therefore not a covered benefit.

Priority Health based its determination on the following provisions of the certificate:

Section 2. Obtaining Covered Services

* * *

C. Referrals.

* * *

... Services with a Non-Participating Provider are covered when the standard of care treatment (medically appropriate treatment) for your condition is not available from a Participating Provider. ... [Underlining added]

Section 6. Covered And Non-Covered Services

* * *

I. Plan Guidelines

* * *

Experimental, Investigational or Unproven Services

* * *

Non-Covered Services

Any drug, device, treatment or procedure that is experimental, investigational or unproven.

Priority Health's medical policy on "Artificial Intervertebral Discs" explains its position (p. 2):

II. POLICY/CRITERIA

A. Artificial Lumbar Discs:

Artificial intervertebral lumbar discs are not a covered benefit because there is insufficient evidence on their long-term safety and effectiveness, including impact on other discs and bony structures of the back.

Finally, Priority Health's medical policy on "Experimental / Investigational / Unproven Care -- Benefit Exceptions" says:

II. POLICY/CRITERIA

- A. Any drug, device, treatment or procedure that is experimental, investigational or unproven is not a covered benefit. A drug, device, treatment or procedure is experimental, investigational or unproven if *any* of the following apply:

* * *

5. Reliable Evidence shows that the prevailing opinion among experts regarding the drug, device, treatment or procedure is that further studies or clinical trials are necessary to determine its toxicity, safety, or efficacy as compared with a standard means of treatment or diagnosis.

Priority Health also referred to analyses by medical review organizations to support its position that the safety and efficacy of lumbar total disc replacement has not yet been established.

Priority Health maintains that its denial of Petitioner's surgery as experimental or investigational was appropriate.

Commissioner's Review

The certificate excludes coverage for services that are deemed experimental, investigational, or unproven. The question of whether the Petitioner's requested surgery is experimental or investigational was presented to an independent review organization (IRO) for review as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The assigned IRO reviewer is board certified in orthopedic surgery and has been in practice for more than 15 years. The IRO reviewer's report said:

The MAXIMUS independent physician consultant, who is familiar with the medical management of patients with the [Petitioner's] condition, has examined the medical record and the arguments presented by the parties.

The results of the MAXIMUS physician consultant's review indicate that this case involves a 45 year-old male who has a history of degenerative disc disease at L4-5 and L5-S1. At issue in this appeal is whether a two level artificial disc replacement procedure is experimental / investigational for treatment of the [Petitioner's] condition.

The MAXIMUS physician consultant explained that there is no long-term outcome data to establish the safety and efficacy of artificial disc replacement at two levels. The MAXIMUS physician consultant also explained that further

follow-up data is needed to establish the long term safety and efficacy of this procedure at this time. The MAXIMUS physician consultant indicated that the long term complications of two level disc replacement have not been established. [Citations omitted]

The IRO reviewer concluded:

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the requested two level artificial disc replacement is experimental / investigational for treatment of the [Petitioner's] condition.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, a recommendation from the IRO 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's analysis is based on extensive experience, expertise, and professional judgment. The Commissioner can discern no reason why the IRO's recommendation should be rejected in the present case.

The Commissioner finds Priority Health's denial of coverage for the two-level artificial disc replacement procedure was consistent with the terms of the certificate.

V ORDER

The Commissioner upholds Priority Health's February 15, 2011, final adverse determination. Priority Health is not required to provide coverage for the requested artificial disc replacement 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 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 Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

R. Kevin Clinton
Commissioner