

STATE OF MICHIGAN
DEPARTMENT OF LABOR & ECONOMIC GROWTH
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX

Petitioner

File No. 89628-001

v

Priority Health

Respondent

**Issued and entered
this 24th day of July 2008
by Ken Ross
Commissioner**

ORDER

**I
PROCEDURAL BACKGROUND**

On May 6, 2008, 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.* On May 13, 2008, after an assessment of the material submitted, the Commissioner accepted the request for external review.

The case required analysis of medical issues. Pursuant to MCL 550.1911(6), the Commissioner assigned the matter to an independent review organization (IRO) which submitted its recommendation to the Office of Financial and Insurance Regulation on May 27, 2008.

**II
FACTUAL BACKGROUND**

The Petitioner has a history of lumbar disc injury and degenerative disc disease. He has tried and failed to find relief with medication therapy, physical therapy, and surgery. He believes

his best option now is artificial disc replacement. He requested authorization and coverage for total disk replacement surgery using a Charité artificial disk.

Priority Health denied coverage for the requested surgery saying it is considered experimental or investigational. The Petitioner completed Priority Health's internal grievance process and received its final adverse determination letter dated April 3, 2008.

III ISSUE

Did Priority Health properly deny the Petitioner coverage for the Charité artificial disk procedure?

IV ANALYSIS

Petitioner's Argument

The Petitioner says he has seen many doctors and had many therapies including, physical therapy (strengthening and flexibility exercises), ice, heat, ultrasound, pelvic traction as well as adjusting his lifestyle. He has tried surgery, epidural injections, and Vicodin to control his pain but nothing seems to help. The Petitioner says the pain is affecting his overall physical functioning, his ability to perform activities of daily living and work, and his quality of life. He says after his MRI and CT scan were reviewed at the XXXXX, the leading authority in artificial disc replacement, it was determined that artificial disc replacement was his best option. He requested coverage for the Charité procedure but Priority Health denied the request.

The Petitioner argues that he was not given a thorough review as promised by Priority Health. He notes that Priority Health, in its grievance procedures, states that it will always get an opinion from a doctor in the same or related specialty that may treat the health issue being reviewed. The Petitioner argues that in his case there was not an orthopedic surgeon or spine specialist but rather an internal medicine physician who lacked the expertise to effectively

evaluate his case. In addition, he does not believe his current MRI and CT scans were reviewed to make a proper clinical recommendation. He also notes that a recent court case showed the terms “investigational” and “long term” are vague. He does not believe that an HMO like Priority Health should second guess the FDA. He also says that a U.S. Court of Appeals decision ruled that the existence of a Phase III clinical trial, such as the one Charité is in, should not be used to determine whether a treatment should be classified as investigational.

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

Priority Health’s Argument

In its final adverse determination, Priority Health stated:

After physician review of the documentation received, we were unable to approve this referral. Priority Health’s Medical Policy #91493-R0, Artificial Intervertebral Disc, specifically states that Artificial Intervertebral Discs are not a covered benefit. There is insufficient evidence on their long-term safety and effectiveness, including impact on other discs and bony structures of the back.

During the grievance process Priority Health asked an independent medical reviewer to decide if the Charité artificial disk was investigational. The independent medical reviewer found:

The available evidence suggests that, compared with spinal fusion, [lumbar total disk replacement] for DDD [degenerative disc disease] using the ProDisc or Charité disc may lead to improved outcomes lasting at least 2 years after surgery. However, the long-term safety of LTDR is still unclear. The evidence from uncontrolled long-term studies suggests that potential degeneration of adjacent discs and facets and wear of the polyethylene part of the disc may occur and that, in some cases, revision surgery may be needed. Long-term follow-up results from randomized controlled studies are not yet available, and it is therefore not known how the long-term safety of LTDR compares with spinal fusion. Furthermore, patient selection criteria still need to be refined. The evidence was further limited by the absence of appropriate control conditions and blind assessments in some studies. Therefore, a **Hayes Rating of C** is assigned to LTDR

using the Charité or ProDisc in patients with DDD, who would otherwise undergo lumbar spinal fusion, as a last-resort treatment after all conservative treatment choices have been exhausted.

A Hayes Rating of C indicates that the procedure has potential but its benefits are unproven.

Priority Health concluded that there were other standard alternatives available for the Petitioner's condition. It believes denial of coverage was appropriate since artificial disk replacement surgery is considered investigational and therefore excluded under the terms of its certificate of coverage.

Commissioner's Review

The Priority Health certificate, in Section 7, "Exclusions From Coverage," says:

The following is a list of exclusions from your Coverage.

* * *

(15) Experimental, Investigational or Unproven Services.

The Petitioner's certificate covers surgical services for the treatment of lumbar degenerative disk disease so long as those services are not considered to be investigational or experimental.

In order to resolve the question of whether the proposed surgery is investigational, experimental, or unproven, the Commissioner obtained the recommendation of an IRO. The review was conducted by a practicing physician who is certified by the American Board of Orthopedic Surgery, a fellow of the American Academy of Orthopedic Surgery and is a clinical instructor at a university-based school of medicine. The IRO physician recommended upholding Priority Health's denial of coverage for the Charité artificial disk.

While acknowledging that preliminary reports on the Charité artificial disk are promising, the IRO physician/reviewer said long-term follow-up data is needed:

This treatment has not been proven effective. There is insufficient peer reviewed medical evidence on the long term safety and efficacy of these devices, including their impact on other adjacent discs and bony structures of the back. There have been significant challenges with respect to prosthetic design and materials because the biomechanics of the intervertebral segment are difficult to replicate.

The standard of care in the orthopedic community is to do a disc excision and fusion of the two levels on either side of the disc that is removed. Arthrodesis of the spine is considered the gold standard for surgical treatment of low back pain. It is not the standard of care to do a cervical disc replacement. There are no good long term studies documenting the efficacy of this operative procedure over more traditional procedures. There are; however, studies documenting increased risk of complication to include nerve injury and component failure.

* * *

Artificial disc replacement is not currently the standard of care secondary to technical difficulties which have yet to be worked out; high reported complication rate; and lack of standardization of revision surgery. At this point, it is apparent that total disc arthroplasty offers no potential greater benefit statistically than fusion.

The IRO concluded, based on the standard to the medical community and available peer reviewed medical literature, that artificial lumbar disc surgery was still investigational and not medically necessary for the Petitioner's condition.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. The IRO's analysis is based on extensive expertise and professional judgment and the Commissioner can find no reason why the IRO recommendation should be rejected. Therefore, the Commissioner accepts the conclusion of the IRO and finds that an artificial disk is investigational in this case and therefore not a covered benefit.

V ORDER

Respondent Priority Health's April 3, 2008, final adverse determination is upheld. Priority Health's denial of the Charité artificial disk was appropriate and consistent with the Petitioner's certificate of coverage.

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 Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.