

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. 119417-001

Humana Insurance Company
Respondent

Issued and entered
this 5th day of August 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On February 4, 2011, XXXXX, on behalf of his patient 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 notified Humana Insurance Company of the external review and requested the information used in making its adverse determination. The Commissioner received Humana's response on February 7, 2011. On February 11, 2011 after a preliminary review of the material submitted the Commissioner accepted the case for external review.

The case involves medical issues so the Commissioner assigned it to an independent review organization, which provided its analysis and recommendation to the Commissioner on February 22, 2011.

II. FACTUAL BACKGROUND

Petitioner has a history of back pain. Having tried numerous treatments, her physician recommended she have back surgery using a procedure known as "interspinous process decompression system" which is also known as "X-STOP." Humana denied authorization for

the surgery because it considers the surgery to be experimental/investigational and therefore not a covered benefit.

The Petitioner appealed Humana's denial of coverage through its internal grievance process. Humana upheld its original determination and issued its final adverse determination letter dated January 10, 2011.

III. ISSUE

Did Humana correctly deny coverage for Petitioner's proposed back surgery?

IV. ANALYSIS

Petitioner's Argument

In a letter dated January 18, 2011, Petitioner's physician, XXXXX, wrote:

[Petitioner] suffers from intermittent neurogenic claudication with moderate physical impairment caused by lumbar spinal stenosis (LSS). . . . A course of conservative medical management including physical therapy/surgical ablation/anti-inflammatories/selective nerve root block/medial branch blocks/ chiropractic care/oral steroids/muscle relaxants/and pain medications has been unsuccessful in treating her debilitating back pain over the last two years. I have determined the best course of action to prevent extension-related compression of nerves in the foraminal spinal canal space and to reduce pain is to use the X-STOP® [procedure].

. . . The X-STOP offers several benefits compared to traditional surgery for lumbar spinal stenosis, including the option of local anesthesia, the potential to be an outpatient procedure, usually no removal of bone or soft tissue allowing for potentially quicker recovery, and fully reversible procedure that does not limit any future non-surgical and surgical treatment options. . . .

Petitioner's physician asserts that the X-STOP procedure is medically necessary for his patient.

Respondent's Argument

In its January 10, 2011, final adverse determination Humana stated:

After a full and fair review of the information, we are unable to approve benefits for the X Stop® Interspinous Process Decompression System.

* * *

This technology is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language. The external independent reviewer also noted approved indications for X-Stop include imaging confirmed diagnosis of Spinal Stenosis. The patient's MRI report of 07/20/09 notes "no stenosis" at L4-5. A study by Verhoof OJ, et al. found a high failure rate of the interspinous distraction device (X-Stop) for the treatment of lumbar spinal stenosis caused by degenerative spondylolisthesis.

Therefore, the X-Stop interspinous process is considered investigational and no benefits are available.

Commissioner's Review

The certificate, on page 50, excludes coverage for treatment that is experimental, investigational, or for research purposes. The certificate defines those terms on page 93:

Experimental or investigational or for research purposes means a drug, biological product, device, treatment or procedure that meets any one of the following criteria, as determined by *us*:

* * *

- Is not identified as safe, widely used and generally accepted as effective for the proposed use as reported in nationally recognized peer reviewed medical literature published in the English language as of the date of service

* * *

The question of whether the Petitioner's surgery is experimental or investigational for treatment of her 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 reviewer is a physician who has been in active practice for more than 15 years, is board certified in orthopedic surgery, and is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included these comments and conclusion:

[T]here are recent reports of increased complications with the X-STOP procedure. . . . [T]here are reports of high failure rates with the X-STOP device due to subsidence. . . . [O]utcomes with the X-STOP procedure have not been demonstrated to be better than simple laminectomy for treatment of the member's condition. . . . [T]he medical literature does not support the use of the X-STOP

procedure at this time. . . . [T]he X-STOP procedure is not the best available treatment for lumbar spinal stenosis at this time. (Daily A. Failure of X-STOP. *J Spine Disord.* 2010.)

The IRO reviewer concluded that the X-STOP procedure is experimental/investigational for the treatment of Petitioner's condition.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded some 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 expertise and professional judgment. The Commissioner can discern no reason why that judgment should be rejected in the present case.

The Commissioner finds that Humana's denial of coverage for the X-STOP surgery is consistent with the terms of the certificate of coverage.

V. ORDER

The Commissioner upholds Humana Insurance Company's adverse determination of January 10, 2011. Humana is not required to provide coverage for the X-STOP procedure.

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.

R. Kevin Clinton
Commissioner