

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. 120683-001

Physicians Health Plan of Mid-Michigan
Respondent

Issued and entered
this 8th day of July 2011
by R. Kevin Clinton
Commissioner

ORDER

I. Procedural Background

On April 19, 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 (PRIRA), MCL 550.1901 *et seq.*

The Petitioner is a member of Physicians Health Plan of Mid-Michigan (PHPMM) a health maintenance organization. Her benefits are defined in the PHPMM's *HMO Plus* certificate of coverage (the certificate). The Commissioner notified PHPMM of the external review and requested the information used in making its adverse determination. The information was received on April 22 and May 5, 2011.

The case involves medical issues so the Commissioner assigned the matter to an independent review organization, which completed its review and sent its recommendation to the Commissioner on May 10, 2011.

II. Factual Background

Petitioner is a 42 year-old female with a history of knee pain. Her physician recommended an autologous chondrocyte implantation (ACI) procedure to treat her condition. Petitioner requested authorization from PHPMM for the proposed treatment. PHPMM denied the request asserting that ACI is unproven in the treatment of Petitioner's condition.

Petitioner appealed the denial through PHPMM's internal grievance process and received its final adverse determination dated February 16, 2011.

III. Issue

Did PHPMM properly apply the terms of Petitioner's certificate in designating the proposed autologous chondrocyte implantation as unproven?

IV. Analysis

Petitioner's Argument

The Petitioner and her physician agree that the ACI procedure is medically necessary for the treatment of her condition. In a letter to PHPMM dated November 29, 2010, the Petitioner's doctor wrote:

. . . We are greatly disappointed that you have denied coverage of a procedure that is receiving overwhelming support in the medical field and, to a patient, a procedure that could minimize if not eliminate the day to day pain that she is experiencing and prevent the progression to the Total Knee Arthroplasty that will certainly be in her near future.

Doctors Koh, Fritz, Gaissmaier and Mollenhauer write the following in the "Techniques in Knee Surgery", March 2009[:]

Autologous Chondrocyte transplantation has good results in the treatment of articular cartilage defects. A novel biphasic collagen scaffold has been devised to reliably deliver cultured chondrocytes to the defect . . . this has resulted in excellent clinical results with a minimum of morbidity and complications in more than 1,000 cases.

[R]ecently published Aetna Clinical Policy Bulletin #0247 states "Aetna considers Autologous Chondrocyte implants medically necessary for repairing cartilage defects of the knee . . . "

We here at XXXXX and XXXXX Center have experienced multiple occasions in which our patients have experienced the benefits of Autologous Chondrocyte Implantation. Experiencing successful pain relief and return to an active lifestyle. . . .

Petitioner's physician believes that the proposed ACI is medically necessary for repairing cartilage defects of the knee.

Respondent's Argument

In its February 16, 2011 final adverse determination, PHPMM denied coverage for the proposed ACI procedure stating:

. . . The original decision to deny your request was upheld because your benefits do not include coverage for unproven services. This decision was based on the PHPMM approved criteria from Hayes, Inc. Hayes is an industry leader providing unbiased, evidence based technology assessment reports. At this time, Hayes concludes that there is insufficient evidence to evaluate the clinical effectiveness of autologous chondrocyte implantation compared with nonsurgical treatment. Your PHPMM Certificate of Coverage (COC) excludes services that are unproven. . . .

Commissioner's Review

The certificate includes the following provision:

Section 2: What's Not Covered – Exclusions

* * *

F. Experimental, Investigational or Unproven Services

Experimental, Investigational and Unproven Services are excluded. The fact that an Experimental, Investigational, or Unproven Service, treatment, device or pharmacological regimen is the only available treatment for a particular condition will not result in Benefits if the procedure is considered to be Experimental, Investigational or Unproven in the treatment of that particular condition. . . .

The question of whether the proposed ACI is unproven in the treatment of Petitioner's condition was presented for review to an independent review organization (a different organization than the organization employed by PHPMM), as required by section 11(6) of PRIRA, MCL 550.1911(6). The IRO reviewer assigned to this case is a practicing physician who is board certified in orthopedic surgery. The IRO reviewer's report included this analysis:

[T]here are no long-term data to demonstrate that autologous chondrocyte implantation is safe and effective for treatment of the member's condition. . . .

[M]ore outcomes data is needed to demonstrate the long-term effectiveness of this procedure. . . . [U]ntil the long-term safety and efficacy of Carticel autologous chondrocyte implantation is established, this procedure remains experimental for the treatment of osteochondral degenerative and traumatic knee conditions. [Citations omitted]

The IRO reviewer concluded that “autologous chondrocyte implantation is experimental/investigational/unproven for treatment of the member’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 that PHPMM’s denial of was consistent with the terms of the certificate.

V. Order

The Commissioner upholds PHPMM’s February 16, 2011, final adverse determination. PHPMM is not required to provide coverage for the proposed autologous chondrocyte implantation 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