

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. 120361-001

Physicians Health Plan of Mid-Michigan
Respondent

Issued and entered
this 20th day of June 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On March 31, 2011, XXXXX, authorized representative and spouse of 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 on a preliminary basis and accepted the request on April 7, 2011.

The Commissioner notified Physicians Health Plan of Mid-Michigan (PHP) of the external review and requested the information used in making its adverse determination. The Office of Financial and Insurance Regulation received PHP's response on April 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 April 21, 2011.

II. FACTUAL BACKGROUND

The Petitioner is a member of Physicians Health Plan of Mid-Michigan (PHP). Her benefits are defined in the PHP Certificate of Coverage (the certificate).

Petitioner has an extensive medical history that includes failed back surgery, lumbar post-laminectomy syndrome, failed spinal cord stimulation, diabetes, and arthritis. She suffers from chronic pain throughout her body. In an effort to manage her pain, Petitioner's physician prescribed an implantable pain pump, a medical device used to deliver small quantities of medication directly to the spinal fluid. The device requires smaller quantities of medication than other delivery methods.

PHP denied coverage ruling that the device is experimental/investigational for the treatment of Petitioner's condition. Petitioner appealed the denial through PHP's internal grievance process. A final adverse determination was issued February 8, 2011.

III. ISSUE

Did PHP properly apply the terms of the certificate in designating the implantable intrathecal pain pump as experimental/investigational?

IV. ANALYSIS

Petitioner's Argument

In an undated letter sent with her request for external review, the Petitioner and her husband say her physicians recently placed her on methadone for pain management because fentanyl was no longer effective. They also say there is evidence that her liver and kidneys are under severe stress at this time and that better pain management with an implantable pain pump could help alleviate the possibility of kidney or liver failure. Petitioner believes her medical history makes her a prime candidate for the implantable intrathecal pain pump and therefore it should not be considered experimental/investigational.

Respondent's Argument

In its February 8, 2011 final adverse determination PHP denied coverage for the pump stating:

. . . The original decision to deny your request was upheld because it is considered unproven and therefore specifically excluded from coverage.

This decision was based on the PHPMM approved criteria from Hayes, Inc. . . . Hayes is an industry leader providing unbiased, evidence based technology assessment reports. Your PHPMM Certificate of Coverage (COC) excludes services that are unproven. . . .

PHP says its denial was based on the following provisions of the certificate:

Section 2: What's Not Covered – Limitations and 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. . . .

PHPMM maintains that it took proper action in denying benefit coverage for Petitioner's implantable intrathecal pain pump as it is considered experimental/investigational and therefore not a covered service.

Section 10 – Glossary of Defined Terms

* * *

Unproven Services – services, including medications that are not consistent with conclusion of prevailing medical research, which demonstrate that the health service has a beneficial effect on health outcomes and that are not based on trials that meet either of the following designs:

- Well-conducted randomized controlled trials. (Two or more treatments are compared to each other, and the patient is not allowed to choose which treatment is reviewed.)
- Well-conducted cohort studies. (Patients who received study treatment are compared to a group of patients who receive standard therapy. The comparison group must be nearly identical to the study treatment group.)

Decisions about whether to cover new technologies, procedures and treatments will be consistent with conclusions of prevailing medical research, based on well-conducted randomized trials or cohort studies, as described.

* * *

Commissioner's Review

Petitioner's certificate excludes coverage for experimental, investigational and unproven services. PHP asserts that the service in question is unproven. To resolve the question of whether the implantable intrathecal pain pump was unproven for Petitioner's condition, the

Commissioner requested the analysis of an independent medical review organization (IRO) pursuant to MCL 550.1911. The review was conducted by a physician in active clinical practice certified by the American Board of Anesthesiology with a subspecialty in pain management. The reviewer is a member of the American Society of Anesthesiology and the International Spine Intervention Society.

The IRO reviewer wrote:

The documentation submitted for review indicates that the enrollee needs an implantable intrathecal pump because she had failed back surgery, lumbar post-laminectomy syndrome, failed spinal cord stimulation and now has intractable pain. There is no documentation that the enrollee had increased pain scores or decreased function after removal of the spinal cord stimulator. The documentation indicates the enrollee has her pain relatively well controlled on oral medications as her average pain score is a 4/10. The recent literature indicates that the implantable intrathecal pain pump has not been proven effective for low back pain. The recent medical literature does not support intrathecal medications for chronic non-cancer pain. An implantable intrathecal opioid pain pump is unproven and not medically indicated per the current standards of care for this [Petitioner's] clinical circumstance at this time.

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 PHP's denial of coverage of the implantable intrathecal pain pump is consistent with the terms of the certificate.

V. ORDER

The Commissioner upholds PHP's final adverse determination dated February 8, 2011. PHP is not required to provide coverage for the implantable intrathecal pain pump requested.

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