

STATE OF MICHIGAN
DEPARTMENT OF ENERGY, 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. 104655-001

v

Physicians Health Plan of Mid-Michigan
Respondent

**Issued and entered
this 22nd day of July 2009
by Ken Ross
Commissioner**

ORDER

**I
BACKGROUND**

On May 4, 2009, 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 11, 2009, after a preliminary review of the material submitted, the Commissioner accepted the request for external review.

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 the information on May 19, 2009.

This case involves medical issues. Therefore, the Commissioner assigned the matter to an independent review organization (IRO) and requested the opinion of a medical expert. On June 11, 2009, the IRO completed its review and sent recommendations to the Office of Financial and Insurance Regulation.

II FACTUAL BACKGROUND

The Petitioner is a member of PHP. His health care benefits are defined in the PHP Certificate of Coverage.

The Petitioner has limb girdle muscular dystrophy (MD), which causes muscle weakness and atrophy. His neuromuscular specialist XXXXX, MD, performed a muscle biopsy that showed he has a type of MD that is associated with alpha dystroglycan deficiency. Dr. XXXXX said, "the most common gene defect causing this problem is a gene deficiency called Fukitin Related Protein (FKRP)." Dr. XXXXX checked the Petitioner for this protein but it was normal. Because there are other genes (POMT1, POMT2 and POMTGnT1) that can cause an alpha dystroglycan deficiency, Dr. XXXXX requested coverage for additional genetic testing in order to find a specific diagnosis and allow for appropriate treatment planning.

PHP denied the request and the Petitioner appealed. At the conclusion of PHP's internal grievance process the Petitioner received a final adverse determination letter dated March 26, 2009.

III ISSUE

Did PHP properly deny the Petitioner coverage for genetic testing under the terms of the certificate?

IV ANALYSIS

Petitioner's Argument

The Petitioner has been diagnosed with MD. He had a muscle biopsy that did not identify the gene responsible for his alpha dystroglycan deficiency. His physician, Dr. XXXXX, wants to perform more genetic testing to try to identify the gene that may be causing his deficiency or to investigate other causes for the deficiency. The Petitioner says his physicians

support the genetic testing as necessary to diagnose his condition. Dr. XXXXX, in a September 23, 2008, letter stated in part:

Our goal is to find a gene mutation in patients like [the Petitioner]. I think it is very important in terms of positioning the patient for potential clinical trials in the future. I will work with [the Petitioner] as closely as possible to try to pin down the diagnosis. We greatly appreciate seeing him.

XXXXX, MD, and XXXXX, DO, agree. In chart notes dated March 2, 2009, Dr. XXXXX stated:

Although previous tests at XXXXX have been negative for 6 of the more common subtypes of Limb Girdle Muscular Dystrophies (LMGD), the biopsy pathology is nevertheless compatible with a dystrophy. This case will be sent out for a second opinion and additional workups.

* * *

Addendum Comment (by Dr. XXXXX): ...

If the clinical phenotype is appropriate, sequencing tests for the remaining dystroglycanopathy genes may be diagnostic.

* * *

Addendum: Talked personally with Dr. XXXXX at XXXXX. The above biopsy findings are suggestive of the FKRP form of limb girdle dystrophy. Dr. XXXXX has agreed to personally see [the Petitioner] and perform the gene sequencing and see if he is candidate for gene transfer trial.

The Petitioner argues that the additional DNA testing (POMT1, POMT2, and POMTGnT1) requested should be covered under his plan “to determine a specific diagnosis to my muscular dystrophy the same as what would be done for individuals who have an inherited risk for breast and ovarian cancer”. He therefore contends the genetic testing at issue is medically necessary and should not be considered clinical research. He therefore wants PHP to provide coverage.

Respondent’s Argument

In its March 26, 2009, final adverse determination, PHP denied coverage for the genetic testing because “services conducted for purposes of medical research are specifically excluded from coverage.”

PHP’s denial of coverage is based on this provision in the certificate:

Section 2: What’s Not Covered – Exclusions

* * *

R. All Other Exclusions

3. Physical, psychiatric or psychological exams, testing, vaccinations, immunizations or treatments when:

* * *

- Conducted for purposes of medical research.

PHP notes that the Petitioner's physicians reference the Petitioner's treatments in terms of "medical advances" and "positioning the patient for potential clinical trials in the future." PHP therefore argues that the requested services are considered experimental and therefore its denial was appropriate.

Commissioner's Review

In order to resolve the question of whether the genetic testing requested by the Petitioner is medically necessary or is for purposes of medical research, the Commissioner obtained the recommendation of an independent review organization (IRO). The review was conducted by a physician who is board certified in medical genetics, and has been in active practice for more than 10 years. The IRO reviewer recommended reversing PHP's denial of coverage for genetic testing.

The IRO reviewer noted that PHP said the genetic testing services are excluded since they are being conducted for the purposes of medical research. The IRO report explained:

The XXXXX physician consultant noted that the [Petitioner] has a muscular dystrophy, which was proven by muscle biopsy. The XXXXX physician consultant also noted that alpha dystroglycanopathies can be further characterized by gene testing. The XXXXX physician consultant indicated that the [Petitioner] did not have a mutation in the FRKP gene, which is one of the most common genes associated with alpha dystroglycanopathy. The XXXXX physician consultant also indicated that mutations in other genes can cause a decreased amount of alpha dystroglycans and muscular dystrophy, including the POMT1, POMT2 and POMTGnT1 genes. The XXXXX physician consultant explained that the POMT1, POMT2 and POMTGnT1 genes can be clinically sequenced. The XXXXX physician consultant also explained that this genetic testing is indicated in a patient with normal FRKP gene sequencing and an alpha dystroglycanopathy, like [the Petitioner]. The XXXXX physician consultant indicated that the [Petitioner] requires identification of the exact genetic defect causing his alpha dystroglycanopathy for development of a long-term treatment plan. The XXXXX physician consultant also

indicated that DNA diagnosis is superior to muscle biopsy in identifying the exact genetic diagnosis. The XXXXX physician consultant explained that the requested genetic testing is medically necessary to allow for the best clinical management of the [Petitioner's] condition.

Pursuant to the information set forth above and available documentation, the XXXXX physician consultant determined that the requested genetic testing is medically necessary for treatment of 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's recommendation should be rejected. Therefore, the Commissioner accepts the conclusion of the IRO and finds that the Petitioner's requested genetic testing is medically necessary.

V ORDER

The Commissioner reverses PHP's March 26, 2009, final adverse determination.

PHP shall cover the Petitioner's diagnostic genetic testing within 60 days of the date of this Order. PHP shall, within seven days of providing coverage, furnish the Commissioner with proof it has implemented this Order.

To enforce this Order, the Petitioner may report any complaint regarding implementation to the Office of Financial and Insurance Regulation, Health Plans Division, toll free 877-999-6442.

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.