

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. 114498-001

v

Physicians Health Plan of Mid-Michigan
Respondent

Issued and entered
this 21st day of January 2011
by Ken Ross
Commissioner

ORDER

I
BACKGROUND

On July 30, 2010, 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 (PRIRA), MCL 550.1901 *et seq.* On August 6, 2010, after a preliminary review of the material submitted, the Commissioner accepted the request.

Physicians Health Plan of Mid-Michigan (PHP) was notified of the request for external review and, on August 17, 2010, furnished the information used in making its final adverse determination.

This case involves medical issues. Therefore, the Commissioner assigned the matter to an independent review organization which submitted its recommendation on August 23, 2010.

II FACTUAL BACKGROUND

The Petitioner is a member of PHP. Her health care benefits are defined in the PHP certificate of coverage (the certificate). Certain provisions in the certificate were amended effective February 1, 2009.

The Petitioner requested genetic testing to determine if she has the BRCA1 or BRCA2 gene mutation which has been linked to the development of hereditary breast and ovarian cancer. PHP denied the request because she did not meet the criteria for the test.

The Petitioner appealed the denial of the testing. At the conclusion of PHP's internal grievance process, PHP issued its final adverse determination letter dated June 2, 2010.

III ISSUE

Did PHP properly deny the Petitioner coverage for BRCA1 and BRCA2 genetic testing under the terms of the certificate?

IV ANALYSIS

Petitioner's Argument

In November 2009, at age 46, the Petitioner was diagnosed with triple negative infiltrating ductal carcinoma (breast cancer) following a lumpectomy. In December 2009 she had a unilateral mastectomy of the right breast.

In a letter to PHP dated April 28, 2010, the Petitioner wrote in part regarding her request for BRCA genetic testing:

I contend that based on my past medical history I am at high risk for breast cancer and/or ovarian cancer and the testing would guide in making decisions about not only my clinical management but that of my 49 year old brother XXXXX, and of the future clinical management of my 6 year old twins, XXXXX and XXXXX.

I have had numerous mammograms over the years where the results have been somewhat inconclusive. Beginning in 2004 I was getting mammography of my right breast every 6 months. I finally discussed this

with Dr. XXXXX in 2006 and asked if there was a better way to assess my breast health. He referred me to a surgeon, Dr. XXXXX, for a consultation. Dr. XXXXX discussed the possibility of performing a breast biopsy or a breast MRI but I was told that I did not meet the criteria for those tests.

My medical records also show that I have had 3 D&C procedures done, the first in 2004, due to having abnormal pap smears. The most recent of these involved removing a cyst which thankfully was benign. The abnormal pap smears bring into question my ovarian health which you mention as one of your criteria for determining the need for BRCA1/BRCA2 testing.

* * *

As I stated earlier in this appeal, the BRCA1/BRCA2 test would no doubt change my medical management. If I had had the test prior to the mastectomy that I underwent on December 4, 2009 and it was found I did have this gene(s), I would've had additional information to discuss with my doctors. It could've been decided at that time whether to opt for continued surveillance of my left breast or maybe have a double mastectomy.

My brother XXXXX was diagnosed with melanoma when he was 38 years old. In my discussions with Ms. XXXXX it is my understanding that there is a link between melanoma and BRCA1/BRCA2. ... One of your criteria for testing is "Women with breast or ovarian cancer diagnosed before the age of 50 and who has a sister, mother, or daughter with breast cancer diagnosed before the age of 50". I believe having a brother who was diagnosed with melanoma at 38 meets the criteria considering the link that exists between melanoma and breast cancer.

The Petitioner believes that the BRCA genetic test is needed because of the history of cancer in her family and in order to guide her treatment plan.

Respondent's Argument

In its June 2, 2010, final adverse determination PHP denied coverage for the BRCA test on the basis that the Petitioner does not meet the criteria in its medical policy:

To meet the required criteria you would need to have a family history of 2 or more cases of breast cancer and one or more cases of ovarian cancer, or be an Ashkenazi Jewish woman with breast cancer diagnosis before age 40 or ovarian cancer diagnosed at any age.

PHP based its decision on the criteria in its medical policy subject "Genetic Testing for BRCA1 or BRCA2 Mutation for Persons at Risk for Breast and Ovarian Cancer." The policy says:

Policy Statement

PHPMM will cover molecular susceptibility testing for breast and/or ovarian cancer ("BRCA testing") where it has been medically proven to be effective and therefore medically appropriate in high-risk individuals and when offered in a setting with adequately trained health care providers to provide appropriate pre-and post-test genetic counseling and performed by a qualified laboratory.

* * *

Coverage Issues:

1. Experimental, Investigational or Unproven Services are exclusions in the enrollee's coverage document.
2. BRCA testing is considered experimental and investigational for the following:
 - Genetic testing in the absence of a personal or family history of breast or ovarian cancers as well as assessment of risk of other cancers such as pancreatic cancer, prostate cancer, and colon cancer.
3. Clinical evidence supports the use of genetic testing for BRCA 1 and BRCA 2 in women who are at high risk for breast and/or ovarian cancer; the purpose of the testing is to guide in making decisions about clinical management. ...

* * *

Clinical Determination Guidelines:

1. Criteria (conditions that must be met) for services to be classified as medically appropriate and covered:

Individuals diagnosed with breast cancer:

- Women with breast cancer diagnosed before the age of 30; or
- Women with breast or ovarian cancer diagnosed before age 50 and who has a sister, mother, or daughter with breast cancer diagnosed before the age of 50; or
- Women with breast or ovarian cancer from a family with two or more cases of breast cancer and one or more cases of ovarian cancer; or
- Ashkenazi Jewish woman with breast cancer diagnosed before age 40 or ovarian cancer diagnosed at any age. ...

PHP considers the BRCA test experimental or investigational if criteria are not met.

PHP says that while the Petitioner was diagnosed with breast cancer before age 50, she does not meet other criteria. PHP notes that its medical policy requires a woman diagnosed with breast or ovarian cancer before age 50 to have a first degree relative (mother, sister, or daughter) diagnosed with breast cancer prior to age 50 as well. PHP also says the results of the genetic test would not alter the Petitioner's treatment.

PHP maintains that the Petitioner does not meet its criteria for coverage and therefore its denial of the genetic test was appropriate.

Commissioner's Review

In order to answer the question of whether genetic testing for BRCA1 or BRCA2 mutation was medically necessary, the Commissioner obtained the recommendation of an independent review organization (IRO) pursuant to Section 11(6) of PRIRA, MCL 550.1911(6).

The review was conducted by a physician who is certified by the American Board of Surgery with a subspecialty certification in general surgery; a member of the American Board of Surgery (diplomate), the American College of Surgeons, the Society of Surgical Oncology, and the American Cancer Society; an associate professor of surgery at two university medical centers; extensively published in the peer reviewed literature; and in active clinical practice. The IRO reviewer recommended overturning PHP's denial of BRCA1 and BRCA 2 testing. The IRO report said:

Currently there is controversy and heterogeneity amongst professional organizations as to the criteria for BRCA testing. Below is a discussion of the most appropriate Cancer Risk Screening Tool in use by the surgical oncology community today.

The Saint Anthony Breast Cancer Risk Screening Tool was designed for use by non-specialists to assist in providing breast cancer risk assessment in a primary care setting. The purpose of this tool is to rapidly identify women in a primary care setting who may be at increased risk for developing breast cancer so that further evaluation can be performed in order to comprehensively assess risk and develop an individualized, risk-adapted disease prevention and screening strategy. For some women at increased risk, lifestyle modifications, risk avoidance and more frequent clinical breast exams may suffice, while others may

also benefit from chemoprevention with a selective estrogen receptor modulator (SERM) such as tamoxifen or raloxifene. Finally, women at the highest end of the risk spectrum who are at risk for hereditary breast cancer syndromes may be appropriate candidates for genetic counseling and consideration of DNA testing for germline mutations in the BRCA1 and BRCA2 genes. ...

* * *

Using the Saint Anthony Breast Cancer Risk Screening Tool, the [Petitioner] has a paternal risk score of 13 which puts her at high risk for harboring a BRCA 1/2 mutation. The Saint Anthony screening tool criteria includes age at menarche, age at first birth, number of biopsies, relatives with a breast cancer diagnosis, number of breasts involved with cancer, and age at diagnosis. This model has been validated in the recent scientific literature in several large studies and is considered as a standard of care by the surgical oncology community.

This patient is HIGH RISK for hereditary breast cancer syndrome: PAT score > 8 and any Gail estimate. Women in this category typically have a lifetime breast cancer risk between 40-85%, and many are also at increased risk for ovarian cancer. Many women in this group have a family cancer history indicating a high probability that a mutation is present in a highly penetrant, autosomal-dominantly inherited cancer susceptibility gene such as BRCA1 or BRCA2. Accordingly, evaluation by a healthcare professional with expertise in genetic counseling for cancer susceptibility is an important component of cancer risk counseling in this situation. Other women in this category are unlikely to harbor mutations in BRCA1 or BRCA2, but are still at high risk for breast cancer due either to polygenic susceptibility from lower penetrance genes or due to high penetrance genes other than BRCA1 or BRCA2. All women in this category benefit from genetic counseling to determine if DNA testing is appropriate and from cancer risk counseling to discuss options for cancer risk-reduction and increased breast cancer surveillance

Additionally, the consensus opinion as currently practiced, according to the standard of care in the surgical oncology community, would hold that BRCA testing is medically necessary for [the Petitioner]. The guidelines that are commonly used for molecular susceptibility testing for breast and/or ovarian cancer ("BRCA testing") detail that the testing is medically necessary in any of the following categories of high-risk adults with breast or ovarian cancer. The guidelines below are from the published literature of the U.S. Preventive Services Task Force, the American College of Obstetricians and Gynecologists, the National Comprehensive Cancer Network (NCCN) guidelines for Breast/Ovarian Genetic Assessment and the American College of Medical Genetics.

BRCA testing is indicated for women with personal history of breast cancer and any of the following:

A. Breast cancer is diagnosed at age 45 years or younger, with or without family history; or

B. Breast cancer is diagnosed at age 50 years or younger, with any of the following:

1. at least one close blood relative with breast cancer at age 50 years or younger; or
2. at least one close blood relative with epithelial ovarian cancer; or
3. bilateral breast cancer, or two primary breast cancers with first primary diagnosed at age 50 years or younger; or
4. limited family structure, or no family history available because patient is adopted.

C. Breast cancer is diagnosed at any age, with any of the following:

1. at least two close blood relatives on the same side of the family with breast cancer +/- epithelial ovarian cancer at any age; or
2. the patient has two breast primaries and also has at least one close blood relative with breast cancer diagnosed at age 50 years or younger; or
3. the patient has two breast primaries and also has at least one close blood relative with epithelial ovarian cancer; or
4. close male blood relative with breast cancer; or
5. at least one first-, second-, or third-degree blood relative with a known BRCA1 or BRCA2 mutation;

Note: Close blood relatives include first-degree relatives (i.e., mother, sister, daughter) and second-degree relatives (i.e., aunt, grandmother, niece), all of whom are on the same side of the family.

Thus, the standard of care for the [Petitioner] would be BRCA 1/2 testing with consideration of prophylactic bilateral mastectomy and bilateral salpingo-oophorectomy if she tests positive. If she is positive, her children should also be tested.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation 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, and is supported by literature. The Commissioner can discern no reason why the IRO's recommendation should be rejected in the present case.

The Commissioner accepts the conclusion of the IRO and finds that the BRCA genetic test is medically necessary for the Petitioner.

V
ORDER

The Commissioner reverses PHP's June 2, 2010, final adverse determination. PHP shall provide coverage for the BRCA1 and BRCA2 testing within 60 days of the date of this Order. PHP shall, within seven days of providing coverage, provide the Commissioner 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 at (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.