

STATE OF MICHIGAN
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES
Before the Director of Insurance and Financial Services

In the matter of:

██████████
Petitioner

v

File No. 150763-001-SF

University of Michigan, Plan Sponsor
and
MedImpact Healthcare Systems, Plan Administrator
Respondents

Issued and entered
this 8th day of January 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On November 6, 2015, Dr. ██████████, authorized representative of ██████████ (Petitioner), filed a request for external review with the Department of Insurance and Financial Services, appealing a claim denial issued by MedImpact Healthcare Systems (MedImpact), the administrator of the Petitioner's prescription drug benefit plan which is sponsored by the University of Michigan.

The request for external review was filed under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* Act 495 requires the Director to provide external reviews to a person covered by a self-funded health plan that is established or maintained by a state or local unit of government. The Director's review is performed "as though that person were a covered person under the Patient's Right to Independent Review Act." (MCL 550.1952) The Petitioner's prescription drug benefit plan is such a governmental self-funded plan.

The Director notified MedImpact of the appeal and asked it to provide the information used to make its final adverse determination. MedImpact furnished its response on November 18, 2015. The Director accepted the Petitioner's request for review on November 30, 2015.

Initially, this case appeared to involve only contractual issues so the Director did not obtain an independent medical review. Upon further evaluation, the Director determined that the case required review by a medical professional and the case was assigned to an independent

review organization for analysis of medical issues. See section 11(7) of the Patient's Right to Independent Review Act, MCL 550.1911(7).

The independent review organization provided its analysis and recommendation to the Director on December 30, 2015.

II. FACTUAL BACKGROUND

The Petitioner has a history of chronic migraine headaches. Since her diagnosis she has tried a variety of medications with limited benefit. In 2012 she was prescribed three compound drugs which she and her doctor believe have successfully treated her migraines: 15% magnesium glycinate, dehydroepiandrosterone, and micronized progesterone.

Beginning July 1, 2015, the University of Michigan's prescription drug plan was amended to exclude coverage for compound drugs. The Petitioner's doctor requested that the University of Michigan and MedImpact continue to provide coverage for the compound drugs. MedImpact denied the request.

The Petitioner appealed MedImpact's ruling with respect to one of the drugs, the 15% magnesium glycinate, through MedImpact's internal grievance process. At the conclusion of that process, MedImpact maintained its denial of coverage and informed the Petitioner of its decision in a letter dated July 15, 2015. There are no similar letters denying coverage for the other two compound drugs that would also be excluded under the benefit plan's July 1, 2015 amendment. However, because all three drugs are compound drugs, the reason for denial and the basis for appeal would be the same for each drug.

In its July 15, 2015 letter, MedImpact did not advise the Petitioner, as it is required to do, that the letter was a final adverse determination. MedImpact also failed to advise the Petitioner of her appeal rights. These notices are required by section 7 of the Patient's Right to Independent Review Act, MCL 550.1907. Because of MedImpact's failure to provide these notices and to clearly state the time limits for filing a request for external review, the Director considers the Petitioner's request for external review to have been timely filed.

III. ISSUE

Did MedImpact properly deny coverage for the compound drugs prescribed for the Petitioner by her physician?

IV. ANALYSIS

Respondent's Argument

In its July 15, 2015 letter to the Petitioner, MedImpact wrote:

Your appeal was not approved. MedImpact's Administrative Review Committee (ARC), consisting of two or more managers, reviewed the appeal and made the following determination(s):

The ARC recommends denial of the appeal. Magnesium glycinate compound is excluded from the pharmacy benefit.

This determination is in accordance with your eligibility for coverage and the terms and conditions of your governing plan document's Exclusions & Limitations section in effect at the time services are received. Your employer or health coverage carrier is responsible for providing your governing plan document to you.

Petitioner's Argument

In the request for external review, the Petitioner's authorized representative wrote:

As of July 1, 2015, compounded medications will no longer be covered by BCN Premier Care/University of Michigan drug coverage. [Petitioner] has used 3 compounded medications since 2012 which has helped her reduce her overall headache burden from chronic migraine headaches. We believe her inability to obtain these compounds will result in serious set back and severe worsening of her mood.

Director's Review

The July 1, 2015 MedImpact notice regarding compound drugs states:

Our records indicate that you recently received a compounded prescription containing at least one bulk chemical. Effective July 1, 2015, compounded claims containing bulk chemical(s) will no longer be covered.

Compounds containing bulk chemicals are no longer eligible for coverage because they are not regulated or approved by the U.S. Food and Drug Administration (FDA), and there is no available clinical evidence to support effectiveness and safety.

According to the plan guidelines, compounds must meet **ALL** of the following criteria to be eligible for coverage:

- The compounded prescription must contain at least two covered ingredients,
- At least one active ingredient must require a prescription by federal law,
- The compounded medication does not require administration by a healthcare professional,
- The active ingredient(s) must be approved by the U.S. Food and Drug Administration (FDA) for medicinal use in the United States,
- The compounded medication is not a copy of a commercially available FDA-approved product,
- The safety and effectiveness for the intended use is supported by FDA approval, or adequate medical and scientific evidence must be available

- in the medical literature, and
- The compound is not intended to replace a drug that has been withdrawn from the market for safety reasons.

In her appeal, the Petitioner does not argue that the prescriptions in question meet the criteria to be eligible for coverage. The Petitioner's argument is that the prescriptions have been effective and, for that reason, should continue to be covered notwithstanding the exclusion stated in the July 1, 2015 MedImpact letter.

The Director assigned the medical issues in this appeal 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 in active practice who is certified by the American Board of Internal Medicine with a subspecialty in clinical neurophysiology. The reviewer is a member of the American Academy of Neurology and the American Epilepsy Society and is published in peer reviewed medical literature.

The IRO reviewer stated that each of the Petitioner's three compound drugs contained a bulk chemical. In addition, the reviewer recommended that MedImpact's denial of coverage be upheld for the following reasons:

The standard of care for a patient with a history of chronic migraine headaches includes using one or several prophylactic medications from different classes, such as anticonvulsants (topiramate, valproic acid), antidepressants (amitriptyline, venlafaxine), and beta blockers (propranolol) or calcium blockers (verapamil), in addition to a triptan (sumatriptan, rizatriptan, frovatriptan) for breakthrough headaches. In cases refractory to these treatment options, as noted in this enrollee's history, onabotulinumtoxinA (Botox) injections can be effective in controlling migraines. The treatment of refractory migraines can be quite complex and includes a multidisciplinary approach. Coexisting factors such as depression, anxiety, and sleep disorders should be identified and treated appropriately. Oral over the counter (OTC) magnesium supplements have been shown to have a modest effect in treatment of migraine headaches, especially during pregnancy where other treatment modalities are quite limited/contraindicated. There is no clear evidence in the literature that hormonal treatments can improve migraine headache control.

[Description of cited medical studies omitted.]

It is the recommendation of this reviewer that the denial issued by MedImpact Healthcare Systems, Inc. for three compounded drugs: Magnesium glycinate 15%, Dehydroepiandrosterone powder, and Bi-est 0.5mg with testosterone (Progesterone micronized powder) be upheld.

While the Director is not required in all instances to accept the IRO's recommendation, the recommendation is afforded deference by the Director. *Ross v Blue Care Network of*

Michigan, 480 Mich 153 (2008). In a decision to uphold or reverse an adverse determination the Director must cite “the principal reason or reasons why the [Director] did not follow the assigned independent review organization’s recommendation.” MCL 550.1911(16)(b). The IRO’s analysis in this case is based on extensive experience, expertise, and professional judgment. The Director finds that, because the prescriptions at issue all contain bulk chemicals, they are not eligible for coverage under the Petitioner’s prescription drug plan.

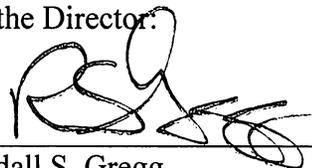
V. ORDER

The Director upholds the Respondents’ denial of coverage for magnesium glycinate 15%, dehydroepiandrosterone powder, and progesterone micronized powder.

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 Department of Insurance and Financial Services, Office of General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Patrick M. McPharlin
Director

For the Director:



Randall S. Gregg
Special Deputy Director