

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. 147012-001

Consumers Mutual Insurance of Michigan
Respondent

Issued and entered
this 27th day of April 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On March 26, 2015, ██████████, authorized representative of ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives medical benefits under an employer group plan underwritten by Consumers Mutual Insurance of Michigan. The Director notified Consumers Mutual of the external review request and asked for the information it used to make its final adverse determination. Consumers Mutual furnished the requested information on March 31, 2015. After a preliminary review of the material submitted, the Director accepted the case for external review on April 2, 2015. Consumers Mutual submitted additional information on April 15, 2015.

The case involves medical issues so the Director assigned the matter to an independent review organization, which completed its review and submitted its recommendation to the Director on April 17, 2015.

II. FACTUAL BACKGROUND

The Petitioner, who is ██████ years old, has had two prior back surgeries (in 2009 and 2014). On January 12, 2015, she had an MRI of the lumbar spine, followed by epidural steroid injections, physical therapy, and medications. On January 23, 2015, she underwent a left lumbar

spinal fusion. The surgery involved bone grafting utilizing Medtronic BioSet procedures and bone morphogenic protein (BMP).

Consumers Mutual, approved coverage for the lumbar spinal fusion, but denied coverage for the BMP and Medtronic BioSet procedures. The Petitioner appealed the denial through the Consumers Mutual internal grievance process. At the conclusion of that process, Consumers Mutual issued a final adverse determination dated February 18, 2015, affirming its denial. The Petitioner now seeks a review of that adverse determination from the Director.

III. ISSUE

Did Consumers Mutual correctly deny coverage for the Medtronic BioSet and BMP portions of the Petitioner's January 23, 2015 surgery?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination, Consumers Mutual wrote:

We sent your case to an Orthopedic Board Certified physician who specializes in spinal fusions. Our appeal physician reviewed your medical information, physician references, and discussed your case with your physician.

The criteria used as part of the review was developed by specialists and peer reviewed articles and patient safety....

Our appeal physician has determined the grafting materials are still not medically necessary at this time. These grafting materials have not been proven safe and effective for the proposed application in peer-reviewed literature. The BMP being used for this case is not in accordance with the United States FDA (Food & Drug Administration) label.

Petitioner's Argument

The Petitioner, through her authorized representative, submitted her medical records for this review. The Petitioner did not submit a written argument explaining why she thought the denial of coverage was improper. However, because the Petitioner and her doctor decided on the technique used in the surgery, it appears that they did not believe the procedures used were experimental.

Director's Review

The Consumers Mutual certificate of coverage, on page 31, excludes coverage for “Experimental, Investigational, or Unproved Services” which the certificate describes as:

Non-Covered Services

Any drug, device, treatment, or procedure that is experimental, investigational, or unproven. A drug, device, treatment or procedure is experimental, investigation [sic], or unproven if one or more of the following applies:

1. The drug or services has not been approved by the Food and Drug Administration (FDA) and, therefore, cannot be lawfully marketed in the United States.
2. An institutional review board or other body oversees the administration of the drug, device, treatment, or procedure or approves or reviews research concerning safety, toxicity, or efficacy.
3. The patient informed consent documents describe the drug, device, treatment, or procedure as experimental or investigational or in other terms that indicate the service is being evaluated for its safety, toxicity, or efficacy.
4. Reliable Evidence shows that the drug, device, treatment, or procedure is:
 - a. The subject of on-going Phase I or Phase II clinical trials; or
 - b. The subject of research, experimental study, or the investigational arm of on-going Phase III clinical trials, or
 - c. Otherwise under study to determine its toxicity, safety, or efficacy as compared with a standard means of treatment or diagnosis; or
 - d. Believed by a majority of experts to require further studies or clinical trials to determine the toxicity, safety, or efficacy of the drug, device, treatment, or procedure as compared with a standard means of treatment or diagnosis.

“Reliable Evidence” includes any of the following:

- Published reports and articles in authoritative medical and scientific literature, or technology assessment and cost effectiveness analysis; or
- A written protocol or protocols used by the treating facility or the protocol(s) of another facility studying the same or a similar drug, device, treatment, or procedure; or
- Patient informed consent documents used by the treating facility or by another facility studying the same or a similar drug, device, treatment, or procedure.

To determine if the BMP/BioSet procedure was experimental, investigational or unproven treatment for the Petitioner's condition, the Director assigned this case to an independent review organization (IRO) as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is a physician in active practice certified by the American Board of Neurological Surgery. The reviewer is a member of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons and is published in peer reviewed medical literature. The IRO reviewer's report included the following analysis and recommendation:

Bone morphogenetic protein (BMP) is Food and Drug Administration (FDA) approved for use in an anterior lumbar interbody fusion at L4-L5 and L5-S1. There is insufficient evidence in the peer-reviewed medical literature that its use in the manner used in this case (TLIF [transforaminal lumbar interbody fusion] and posterolateral fusion) is safe and efficacious. This is an off-label use of the product. That is, its use in this manner does not have strong research-based evidence to permit conclusions and/or clearly define long-term effects and impact on health outcomes. There have, in fact, been some complications reported with the use of BMP in a TLIF/posterior lumbar interbody fusion (PLIF) construction, (in particular, ectopic bone formation causing symptoms), so that the use of BMP in such a way has not been fully defined. In fact, there is an ongoing clinical trial that is looking to characterize the radiculitis following the use of BMP in a TLIF. The enrollee had degenerative disc disease (DDD) and was symptomatic from the L5-S1 for the third time in a short time span. The standard of care would be to perform a lumbar fusion. If performing a TLIF, then standard allograft/autograft can be used to achieve fusion.

The medical evidence does not demonstrate that the expected benefits of the health care service request is more likely to be beneficial to the enrollee than any available standard health care service. This enrollee underwent a single-level fusion with no documented reason that BMP should have been used over standard fusion methods.

* * *

The use of BMP in spinal fusion, other than when used anteriorly at L4-L5 or L5-S1, has not been FDA approved. There is a humanitarian device exemption noted in those cases that have failed posterolateral fusion and have risk factors for nonunion; this is only in special circumstances. The enrollee does not meet any of these criteria and the grafting material (BMP) and Medtronic Bioset performed on January 23, 2015 during the lumbar spinal fusion was experimental/investigational for the treatment of the enrollee's condition.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Consumers Mutual Insurance of Michigan for the grafting material (BMP) and Medtronic Bioset performed on January 23, 2015 during the lumbar spinal fusion be upheld.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the recommendation is afforded deference by the Director. 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 is based on extensive experience, expertise, and professional judgment and is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15). The Director can discern no reason why the IRO's recommendation should be rejected in the present case.

The Director finds that Consumers Mutual's denial of coverage is consistent with the terms of the certificate.

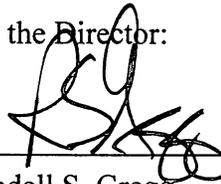
V. ORDER

The Director upholds Consumers Mutual Insurance of Michigan's February 18, 2015 final adverse determination.

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.

Annette E. Flood
Director

For the Director:



Randall S. Gregg
Special Deputy Director