

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. 147850-001

Federated Mutual Insurance Company
Respondents

Issued and entered
this 5th day of August 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

The Patient's Right to Independent Review Act (MCL 550.1901 *et seq.*) authorizes the Director of Insurance and Financial Services to review denials of coverage for health care services. These external reviews are initiated by policyholders or an authorized representative once a coverage denial has been reviewed by the insurer in its internal grievance process.

On June 8, 2015, ██████████ (Petitioner) completed a request for an external review with the Director of Insurance and Financial Services. The Petitioner receives health care benefits through Federated Mutual Insurance Company (Federated). The benefits are described in Federated's *Group Health Insurance Certificate of Coverage*.

The Director notified Federated of the external review requests and asked for the information it used to make its final adverse determination. Federated submitted material on June 11, 2015. The Director accepted the request on June 15, 2015.

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on July 27, 2015.

II. FACTUAL BACKGROUND

The Petitioner has osteoarthritis of the right knee. On December 9, 2014, her physician administered three injections of Euflexxa simultaneously under ultrasound guidance. The amount charged for the injections was \$2,082.71. Federated denied coverage, ruling that three simultaneous Euflexxa injections were not medically necessary and did not reflect accepted standards of medical practice.

The Petitioner appealed the denial through Federated's internal grievance process. At the conclusion of that process, Federated issued its final adverse determination dated June 3, 2015, affirming its decision. The Petitioner now seeks a review of that adverse determination from the Director.

III. ISSUE

Did Federated correctly deny coverage for the Petitioner's Euflexxa injections?

IV. ANALYSIS

Federated's Argument

In its final adverse determination, Federated indicated that it requested an outside medical review of the Petitioner's treatment. The review was performed by the Medical Review Institute of America, an independent review organization. Federated asked the reviewer whether simultaneous Euflexxa injections met accepted medical standards of practice and medical necessity for this patient's medical condition. Federated's reviewer concluded:

The Euflexxa injection that was administered as a 3-in-1 injection does not meet accepted medical standards of practice and medical necessity for this patient's medical condition.

The patient had evidence of symptomatic osteoarthritis of the right knee that was elected for treatment with Euflexxa viscosupplementation. Per the Euflexxa FDA approved package insert "EUFLEXXA comes in pre-filled syringes containing 2 ml (about half a teaspoon) of product. EUFLEXXA is given by injection directly into the knee joint by a doctor or other qualified healthcare professional. EUFLEXXA is injected into your knee once a week, for a total of three injections."

There are no well conducted studies in published peer reviewed literature of the safety, efficacy, and improved or equal long term outcomes of a single staged (3 in 1) Euflexxa injection over the standard of care, FDA approved, single vial injection weekly for 3 weeks. Thus, the 3 in 1 injection does not meet accepted medical standards of practice and medical necessity for this patient's medical condition.

Petitioner's Argument

In a letter dated May 6, 2015 submitted with her request for external review, the Petitioner wrote:

I am requesting a second level review of this claim for the following reasons:

1. On December 9, 2014 when I went to [REDACTED] and saw [REDACTED] [REDACTED] for problems with both my knees options were discussed

with me. As you will see from the enclosed consultation notes from my visit, [REDACTED] suggested I have a 3 in 1 injection of Euflexxa. At no time was I made aware by the doctor, or her staff, that there was the option of having 1 injection every week for 3 weeks of this medication. Since this information was never presented to me by [REDACTED] or her staff, I was not able to choose.

2. On December 9, 2014 when I was referred by [REDACTED] to see [REDACTED] to have the ultrasound-guided right knee joint injection administered I was informed the injectate would be three vials of Euflexxa given at the same visit as you will see in the enclosed notes from [REDACTED]. At no time was I informed by [REDACTED] or his staff, that I could choose to have 1 injection every week for 3 weeks of this medication. Since this information was never presented to me by [REDACTED] or his staff, I was not able to choose.
3. When my claim was first submitted to Federated Insurance by [REDACTED] and I received my initial EOB I contacted Federated Insurance and asked why this injection was not covered. No clear explanation was given. This made it very difficult to determine what documentation I needed to provide to get coverage and what the problem was.

Enclosed with this letter, and my clinical notes from both doctors at [REDACTED] pertaining to this case, is a letter from [REDACTED] stating why she chose to have me receive the 3 in 1 injection of Euflexxa. Since [REDACTED] is known worldwide as an innovator in quality patient oriented healthcare I request you reconsider your position on this claim.

In a letter explaining the need for the injection technique, [REDACTED] wrote:

[Petitioner] is a patient under my care for osteoarthritis of her knee. This involves in particular the patellofemoral portion of the right knee. As part of her treatment regimen, she was sent to physical therapy and also injected with Euflexxa, a form of viscosupplementation.

The Euflexxa can be given one small vial once a week for three weeks. It can also be given all three vials at one time through one injection. Our choice here is to do the triple injection. It not only prevents the patient from having to return to the clinic two additional times. It is also less expensive for the patient since we do these injections with ultrasound guidance.

The injection was medically necessary for her osteoarthritis. It was also given efficiently during one treatment session as opposed to three. This ultimately reduced the cost of the treatment for both the patient and the insurance company. I encourage you strongly to cover this injection as a benefit extended to her by your company.

Director's Review

The certificate of coverage contains the following provision:

SECTION VII - EXCLUSIONS

* * *

The following exclusions apply to all coverages described in the **policy**. Coverage is not provided for and no **benefits** will be paid for:

* * *

43. Treatment, services or supplies that do not meet generally accepted standards of practice in the United States medical community. Treatment, services or supplies that are not provided in accordance with generally accepted medical practice and management currently used in the United States. Treatment services or supplies that are not provided at the most appropriate level of medical care that is needed to provide safe, adequate and appropriate diagnosis or medical treatment.

To determine whether the Euflexxa injections were medically necessary and met an acceptable standard of medical practice for the Petitioner's condition, the Director presented the Petitioner's medical records 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 selected by the Director for this review, Permedion, was a different organization than the one utilized by Federated.)

The Permedion reviewer is a licensed physician in active clinical practice who is certified by the American Board of Orthopaedic Surgery and is published in peer reviewed medical literature. The Permedion report included the following analysis and recommendation:

It is the determination of this reviewer that the Euflexxa injection does not meet the accepted medical standards of practice or medical necessity for the treatment of the enrollee's condition.

* * *

There is no medical literature available from the National Institutes of Health, or PubMed supporting the three-in-one technique used by [REDACTED]. The manufacturer only recommends one injection weekly for three weeks. The accepted standard of practice is to follow the manufacturer's guidelines when there is no contravening peer reviewed medical literature.

The manufacturer states on its website the following...

Euflexxa is injected into the space in the knee joint. Treatment consists of three injections, one injection per week for three weeks.

Some people experience moderate pain relief after the first or second injection of Euflexxa, but most people experience significant relief after the third (last) injection. The approved dosing regimen for Euflexxa is three injections. Even if pain is

experienced after the first or second injection of Euflexxa, all three injections should be received for maximum benefit."

* * *

Based on the documentation submitted for review and the current standards of care, the manufacturer's guidelines recommend the approved dosing regimen for Euflexxa is one injection weekly for three weeks.

* * *

It is the recommendation of this reviewer that the denial issued by Federated Mutual Insurance Company for Euflexxa injection, 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. In addition, the IRO's recommendation is not contrary to any provision of the certificate which describes the Petitioner's benefits. 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 the Petitioner's simultaneous Euflexxa injections were not medically necessary or the standard of care for treatment of the Petitioner's condition.

V. ORDER

The Director upholds Federated Mutual Insurance Company's final adverse determination of June 3, 2015.

This is a final decision of an administrative agency. 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 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