

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. 145930-001-SF

University of Michigan, Plan Sponsor

and

Blue Cross Blue Shield of Michigan, Plan Administrator,

Respondents.

---

Issued and entered  
this 26<sup>th</sup> day of January 2015  
by Randall S. Gregg  
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On January 22, 2015, ██████████, authorized representative of ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* The Director accepted the request on January 22, 2015.

The Petitioner receives health care benefits through a group plan sponsored by the University of Michigan (the plan), a self-funded governmental health plan subject to Act 495. Blue Cross Blue Shield of Michigan (BCBSM) administers the plan. The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM responded on January 22, 2015.

Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Director to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* Because a medical issue was involved, the Director assigned the case to an independent review organization which provided its recommendation to the Director on January 23, 2015.

## II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in BCBSM's *Community Blue Group Benefits Certificate ASC*<sup>1</sup> (the certificate). The coverage includes specialty pharmaceuticals.

The Petitioner is pregnant. Her physician asked BCBSM to authorize and cover the specialty drug Makena, a synthetic form of the female hormone called progesterone. The drug is used to lower the risk of premature birth. BCBSM denied the request, saying the Petitioner did not meet its criteria for use of the drug.

The Petitioner appealed. At the conclusion of an expedited review through its internal grievance process, BCBSM issued a final adverse determination dated January 16, 2015, upholding its denial. The Petitioner now seeks a review of that adverse determination from the Director.

## III. ISSUE

Did BCBSM correctly deny authorization and coverage for Makena?

## IV. ANALYSIS

### Petitioner's Argument

On the request for an external review her doctor stated:

... [The Petitioner] had a previous pregnancy complicated by cervical insufficiency. Based on the New England Journal of Medicine publication by Meis, et al (2003) and the ... publication (Practice Bulletin #130; 2012), the patient will benefit from 17-OH Progesterone Caproate [Makena] for reduction of prematurity with the current pregnancy.

Irrespective of the number of fetuses she is currently carrying, the data support clear benefit of 17-OH P in a patient like [the Petitioner], with a history of cervical insufficiency.

Medical records in the file indicate that the Petitioner had a pregnancy terminated at about 24 weeks gestation in 2012 because of advanced cervical dilation. The Petitioner's doctor believes that Makena is therefore medically necessary and appropriate.

---

<sup>1</sup> BCBSM form no. 457F, effective 7/14.

BCBSM's Argument

In its final adverse determination, BCBSM's representative explained to the Petitioner:

A Clinical Pharmacist reviewed the appeal/medical documentation provided and your health care plan benefits for [BCBSM]. Based on the review the following was determined:

The Medical Policy for Makena requires that the patient is pregnant with one baby. You are pregnant with multiple. And, the Medical policy for Makena requires that the patient does not have any condition(s) that can result in pre-term delivery (e.g. incompetent, shortened or abnormal shaped cervix or a cerclage is in place). We have chart notes to indicate that you have a cerclage in place and a history of shortened cervix.

Therefore, because the criteria for preauthorization have not been met, our denial must be maintained. If you choose to obtain the specialty drug, you will be responsible for the full cost.

Director's Review

The certificate covers specialty pharmaceuticals when preauthorization requirements are met. BCBSM declined to authorize Makena because it said the Petitioner did not meet the criteria for its use. Those criteria are found in BCBSM's pharmaceutical policy for Makena.

To answer the questions of whether the Petitioner meets BCBSM's medical policy criteria or if Makena is otherwise medically necessary to treat the Petitioner's condition, the Director presented this matter to an independent review organization (IRO) for analysis and a recommendation as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is board certified in obstetrics and gynecology and in maternal and fetal medicine, has been in practice for more than 15 years, and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis and recommendation:

**Recommended Decision:**

The MAXIMUS physician consultant determined that Makena is not medically necessary for treatment of the member's [i.e., Petitioner's] condition.

**Rationale:**

\* \* \*

The results of the consultant's review indicate that this case involves a [redacted] year-old G4 P0120 female at 16 weeks gestation with a monchorionic diamniotic twin

gestation. At issue in this appeal is whether Makena is medically necessary for treatment of the member's condition.

The member's medical history is significant for Sjogren's syndrome with anti-Ro and anti-La antibodies. The member's obstetrical history is significant for a 23 week induction termination due to advanced cervical dilation after a shortened cervix was noted on ultrasound at 22 weeks and she was started on vaginal progesterone. Following that pregnancy, the member had a consultation that recommended 17 hydroxyprogesterone (Makena) for future pregnancies for presumed cervical insufficiency/history of preterm labor.

The MAXIMUS physician consultant explained that while this recommendation would have been appropriate if the member's subsequent pregnancy was of a single gestation, this is not the appropriate recommendation for a twin gestation. The physician consultant indicated that the 2003 study that demonstrated a reduction in the incidence of recurrent preterm delivery with 17 hydroxyprogesterone was done only in singleton gestations. The consultant also indicated that subsequent studies in twin gestations have not shown any prolongation of pregnancy with 17 hydroxyprogesterone therapy.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Makena is not medically necessary for treatment of the member's condition. [Citations omitted]

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 Petitioner's certificate of coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that Makena is not medically necessary for the Petitioner's condition and is therefore not a covered benefit.

#### V. ORDER

The Director upholds BCBSM's January 16, 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 Michigan 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:

A handwritten signature in black ink, appearing to read 'R. S. Gregg', is written over a horizontal line.

Randall S. Gregg  
Special Deputy Director