

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX

Petitioner

v

File No. 118693-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 18th day of May 2011
by R. Kevin Clinton
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On December 27, 2010, XXXXX, authorized representative of 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, MCL 550.1901 *et seq.* The Commissioner reviewed the material submitted and accepted the request on January 5, 2011.

The Commissioner immediately notified Blue Cross Blue Shield of Michigan (BCBSM) of the external review and requested the information it used in making its adverse determination.

The Commissioner assigned the case to an independent review organization (IRO) because it involved medical issues. The IRO provided its analysis and recommendation to the Commissioner on January 20, 2011.

II
FACTUAL BACKGROUND

The Petitioner receives health care benefits as an eligible dependent. The terms of her

coverage are found in BCBSM's *Community Blue Group Benefits Certificate* (the certificate).

The Petitioner has been diagnosed with idiopathic gastroparesis and her physician's recommended surgery to implant a gastric electrical stimulator. The request for authorization for the surgery was denied by BCBSM on the basis that the device is experimental for treatment of her condition.

The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM held a managerial-level conference on October 28, 2010, and issued a final adverse determination dated November 18, 2010, upholding its position.

III ISSUE

Did BCBSM properly deny authorization for the Petitioner's surgery to implant a gastric electrical stimulator?

IV ANALYSIS

Petitioner's Argument

The Petitioner's authorized representative disputes BCBSM's general contention that the gastric electrical stimulator is experimental and specifically disputes BCBSM's argument that there was no "quality abnormal emptying" time study that demonstrated the need for this device.

The representative says that BCBSM completely discounted an abnormal gastric emptying study conducted in 2007 on the basis that it does not meet the standard for testing at 2 and 4 hours; other gastric emptying studies were disregarded because either they were conducted while the Petitioner was on medication or she vomited the radiolized egg before the test was concluded.

According to the representative, the Petitioner's gastroparesis is so severe that she cannot go 10-14 days without medication in anticipation of having a gastric emptying study performed, or if she did, she would vomit the radiolized egg. This creates "an impossible Catch-22" for the Petitioner: she is too sick to have the test done and therefore BCBSM says that she cannot prove

that she needs a gastric electric stimulator.

The Petitioner has been diagnosed with idiopathic gastroparesis by several doctors and the condition has proven to be refractory to all medication. The only treatment that she has not yet tried is gastric electrical stimulator. The Petitioner's representative argues because this device is both medically necessary and well founded in the medical literature, BCBSM's denial should be overturned.

BCBSM's Argument

BCBSM says that the certificate, in *Section 6: General Conditions of Your Contract*," excludes experimental treatment from coverage:

Experimental Treatment

Services That Are Not Payable

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment. . . . In addition, we do not pay for administrative costs related to experimental treatment or for research management.

In Section 7, "experimental treatment" is defined as:

Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as "investigational" or "experimental services."

BCBSM's medical director is responsible for determining whether the use of any service or device is experimental based on medical criteria and guidelines. Under BCBSM's medical policy, coverage for gastric electrical stimulators for gastroparesis remains experimental or investigational because its safety and effectiveness have not been proven and there is very little available published evidence that this procedure is effective to improve gastric emptying and mobility. While experience with gastric stimulation is increasing, BCBSM says data is still inadequate to permit scientific conclusions.

BCBSM says the Petitioner underwent several tests. However, there were no recommendations from physicians at either the XXXXX or the XXXXX for the gastric stimulator.

BCBSM says the emptying study at the XXXXX was also inconclusive.

Commissioner's Review

The certificate is clear that experimental procedures are not a covered benefit. Therefore, the question of whether the Petitioner's gastric electrical stimulator is experimental for treatment of her condition was presented 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 practicing physician who is board certified in gastroenterology that has been in practice for more than ten years.

The IRO report offered the following conclusion and analysis:

The MAXIMUS physician consultant noted that the [Petitioner's] diagnosis of idiopathic gastroparesis is based on a gastric emptying test that demonstrated delayed emptying of solids. The MAXIMUS physician consultant also noted that the [Petitioner] has failed treatment with promotility agents and anti-emetics. The MAXIMUS physician consultant further noted that the [Petitioner] did not benefit from a Botox injection to the pylorus. The MAXIMUS physician consultant indicated that the [Petitioner] has remained symptomatic on a "gastroparesis diet." The MAXIMUS physician consultant also indicated that the [Petitioner] has been using Vicodin for abdominal pain.

The MAXIMUS physician consultant explained that controlled data for the gastric electrical stimulator has been disappointing. The MAXIMUS physician consultant indicated that a recent study involving patients with diabetic gastroparesis, essentially showed no difference when the stimulator was turned on or off. The MAXIMUS physician consultant noted that in this study, patients improved post-operative, suggesting a placebo response to laparotomy. [Citation omitted] The MAXIMUS physician explained that while open label data were encouraging, the available studies do not demonstrate that the use of gastric electrical stimulation results in a statistically significant benefit. [Citation omitted]

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that gastric electric stimulation is experimental / investigational for treatment of the [Petitioner's] condition.

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 reviewer’s analysis is based on expertise and professional judgment and the Commissioner can discern no reason why the recommendation should be rejected in the present case.

The Commissioner accepts the IRO reviewer’s conclusion and finds that gastric electrical stimulator is experimental for treatment of the Petitioner’s condition and is therefore not a covered benefit under the terms of the certificate.

**V
ORDER**

Respondent BCBSM’s November 18, 2010, final adverse determination is upheld. BCBSM is not required to authorize coverage for the Petitioner’s gastric electrical stimulation.

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 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.

R. Kevin Clinton
Commissioner