

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. 146652-001

Blue Cross Blue Shield of Michigan

Respondent

Issued and entered
this 6th day of April 2015
by Joseph A. Garcia
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On March 5, 2015, ██████████, authorized representative of her patient ██████████ (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.* After a preliminary review of the material submitted, the Director accepted the request on March 12, 2015.

The Petitioner receives prescription drug benefits through a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM provided its response on March 18, 2015.

To address the medical issues in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on March 26, 2015.

II. FACTUAL BACKGROUND

The Petitioner's prescription drug benefits are defined in BCBSM's *Simply Blue Group Benefits Certificate LG¹* (the certificate).

¹ BCBSM form no. 778E, approved 02/15, effective 2015.

The Petitioner has gastroparesis, a condition which prevents the stomach from emptying properly. When she failed treatment with domperidone and erythromycin and could not tolerate Reglan, her doctor requested authorization for an endoscopy with Botox injection in the pylorus region of the stomach to treat her condition. BCBSM denied the request, saying the procedure was investigational and therefore not a benefit.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process BCBSM affirmed its denial in a final adverse determination dated December 22, 2014. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny authorization for the use of Botox in this procedure?

IV. ANALYSIS

Petitioner's Argument

The Petitioner's authorized representative stated in her request for an external review:

This patient has gastroparesis as diagnosed by a GES [*gastric emptying study*]. She . . . was told by a pharmacist it is not advised to take medication which prolong one QT interval [*a measure of the heart's electrical cycle*]. This eliminates Reglan & Domperidone as treatment. Erythromycin is not effective. . . . Therefore EGP Botox would greatly benefit the patient.

BCBSM's Argument

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

. . . After review, the denial of prior authorization for Botox is maintained because you do not meet the medical criterion for approval of Botox. The medical policy for Botulinum Toxin Type A (Botox) does not allow this medication to be used for investigational indications. Gastroparesis is considered investigational use.

You are covered under *Simply Blue Group Benefits Certificate LG for Large, Insured Group Customers*. On page 77, in **Section 3: What BCBSM Pays For**, under **Prescription Drugs: Prior Authorization for Specialty Pharmaceuticals**, it explains the following:

- Prior authorization is required for select specialty pharmaceuticals. Only FDA-approved medications are eligible for prior authorization and of those drugs, only the specialty pharmaceuticals that meet BCBSM's medical policy criteria for treatment of the condition will be preauthorized.

Further, on page 137, in **Section 6: General Condition of Your Contract**, under **Experimental Treatment**, it states that we do not pay for experimental treatment, including experimental drugs.

Director's Review

The certificate (p. 132) has this exclusion for 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.

“Experimental treatment” is defined in the certificate (p.150) as

[t]reatment 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.”

The question of whether Botox is investigational for use as requested to treat the Petitioner's condition was presented 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 board certified in internal medicine with a subspecialty certification in gastroenterology and is in active practice. The IRO report made this recommendation:

Reviewer's Decision and Principal Reasons for the Decision

It is the determination of this reviewer that Botox is experimental/investigational and therefore not medically necessary for the treatment of the enrollee's condition.

Clinical Rationale for the Decision:

* * *

The AGA [*American Gastrointestinal Association*] concludes as follows:

"Intrapyloric injection of botulinum toxin is not recommended for patients with gastroparesis based on randomized controlled trials. (Strong recommendation, high level of evidence)."

Several studies have tested the effects of pyloric injection of botulinum toxin in patients with diabetic and idiopathic gastroparesis. These studies have all been unblinded with small numbers of patients from single centers and have observed mild improvements in gastric emptying and modest reductions in symptoms for several months. Moreover, the American Gastroenterological Association has concluded that double-blind controlled studies are needed to support the efficacy of this treatment.

* * *

The enrollee has diabetes and gastroparesis. The enrollee has failed domperidone and erythromycin and cannot tolerate reglan. At this time there is inadequate support in the medical literature to conclude that the provision of Botox for gastroparesis has a positive effect on healthcare outcomes. There are small studies with limited conclusions and there are no double-blinded studies of sufficient patient enrollment to draw definitive conclusions. Therefore, it is considered experimental in nature and as such, not medically necessary at this time for its use in this enrollee. [References 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 IRO's 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 recommendation 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 and finds that Botox is investigational for treatment of the Petitioner's condition and is therefore not a covered benefit under the certificate.

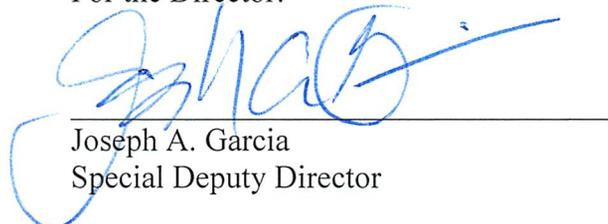
V. ORDER

The Director upholds BCBSM's final adverse determination of December 22, 2014.

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:



Joseph A. Garcia
Special Deputy Director