

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. 154517-001-SF

State of Michigan, Plan Sponsor
and
Blue Cross Blue Shield of Michigan, Plan Administrator
Respondents

Issued and entered
this 11th day of August 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On July 11, 2016, ██████████ (Petitioner) filed a request for external review with the Department of Insurance and Financial Services. The request for review concerns a denial of coverage for a medical procedure to treat the Petitioner's gastroesophageal reflux disease. The denial was issued by Blue Cross Blue Shield of Michigan (BCBSM), the administrator of the Petitioner's health benefit plan which is sponsored by the State of Michigan.

The request for external review was filed under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* Act 495 requires the Director to provide external reviews to a person covered by a self-funded health plan that is established or maintained by a state or local unit of government. The Director's review is performed "as though that person were a covered person under the Patient's Right to Independent Review Act." (MCL 550.1952) The Petitioner's health benefit plan is such a governmental self-funded plan. The plan's benefits are described in BCBSM's *State Health Plan PPO* benefit guide.

On July 18, 2016, after a preliminary review of the information submitted, the Director accepted the request for review. The Director notified BCBSM of the appeal

and asked it to provide the information used to make its final adverse determination. BCBSM submitted its response on July 27, 2016.

This case involves medical issues so the Director assigned it to an independent review organization which provided its analysis and recommendation to the Director on August 1, 2016.

II. FACTUAL BACKGROUND

The Petitioner is 64-years old and has gastroesophageal reflux disease (GERD). Her doctor recommended the Stretta procedure, an endoscopic surgery, to treat her condition. BCBSM denied coverage, ruling that the procedure was investigational for the treatment of the Petitioner's condition.

The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM issued a final adverse determination on May 16, 2016 affirming its denial. The Petitioner now seeks the Director's review of that final adverse determination.

III. ISSUE

Is the Stretta procedure investigational/experimental for the treatment of the Petitioner's condition?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination to the Petitioner, BCBSM wrote:

The BCBSM/ Blue Care Network Joint Uniform Medical Policy Committee (JUMP) has determined that this procedure is considered investigational and/or experimental. Investigational and/or experimental services are not a benefit under your health care plan.

* * *

An investigational status means that the safety and effectiveness of a particular technology has not been definitively determined ... Investigational medical policies are reviewed regularly to guarantee that the investigational status continues to be supported by the evidence.

A medical consultant, board-certified M.D. in General Surgery reviewed your appeal and your health care plan benefits for BCBSM and determined the following:

Your doctor is requesting prior authorization to complete the Stretta procedure (procedure code 43257), which is a minimally invasive endoscopic procedure to treat your gastrointestinal esophageal reflux disease (GERD). According to the BCBSM medical policy titled, "Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease," the Stretta procedure is considered investigational and/or experimental. It has not been scientifically demonstrated to be as safe and effective for the treatment of GERD as a conventional medical and/or surgical procedure.

Petitioner's Argument

With her request for review, the Petitioner submitted copies of medical literature concerning the Stretta procedure. The Petitioner states that this material shows that the procedure is not experimental as BCBSM has claimed. In a June 27, 2016 letter filed with the external review request, the Petitioner wrote:

I feel the Stretta procedure is the best option for me as the patient because I remain symptomatic despite a maximum course of proton pump inhibitors. I am still experiencing GERD symptoms that are unresponsive to prescribed medication. The only other option to relieve my symptoms is a fundoplication surgery. The surgery is invasive, requires a hospital stay and is associated with known complications.

According to my physician ... fundoplication does have a role for some patients with drug resistant GERD, i.e. patients with severe GERD symptoms, esophagitis or large hiatal hernia. However, quite frankly, for many patients fundoplication represents overkill. I have discussed both the Stretta procedure and fundoplication surgery with my physician ... and we agree that I would like to opt for the Stretta procedure.

Director's Review

The *State Health Plan PPO* benefit guide (page 38) states that no coverage is provided for "services, care, devices, or supplies considered experimental or investigational" and for "services and supplies that are not medically necessary according to accepted standards of medical practice."

Whether the Stretta procedure is experimental/investigational and whether it is medically necessary for treatment of the Petitioner's condition were questions 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 physician in active practice for more than 12 years who is board certified in surgery and critical care and is familiar with the medical management of patients with the Petitioner's condition. The IRO physician reviewer's report included the following analysis and recommendation:

According to the information provided for review, the member has undergone a Bilroth 1 procedure in the past as well as a transoral incisionless fundoplication (TIF) and the LINX procedure. The last medical record provided for review was from August 2015. It should be noted that the attending physician recommended a repeat TIF at that time.

[T]he Stretta procedure is endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) in a consensus statement from 2013 ... [M]ore than 30 peer reviewed studies, including 4 adequately powered randomized controlled studies, a comprehensive meta-analysis and multiple prospective clinical trials have documented safety and efficacy of the Stretta procedure ... [D]urable treatment outcomes to at least 48 months have been demonstrated in multiple studies with significant reduction in or elimination of medication used to treat the symptoms of gastroesophageal reflux disease, as well as improvement in quality of life and symptom scores ... [T]he Stretta procedure may be recommended as a therapeutic option for patients with gastroesophageal reflux disease who meet current indications and patient selection criteria and chose endoluminal therapy over laparoscopic fundoplication and therefore, the Health Plan's medical policy criteria regarding this procedure are not consistent with the standard of care ...

However ... based on the available records, medical necessity for this procedure has not been established in this member's case ... [T]he information provided for review includes no discussion of the member's anatomy ... [T]he medical records do not include a description of why a minimally invasive non-anatomic therapeutic procedure would be likely to be successful after 3 other procedures that alter functional anatomy have failed.

Pursuant to the information set forth above and available documentation ... the Stretta procedure is not investigational and not medically necessary for treatment of the member's condition.

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 review is based on extensive experience, expertise, and professional judgment. The Director can discern no reason why the IRO's recommendation should be rejected in the present case. The Director finds that, while the Stretta procedure is not experimental/investigational, it is not medically necessary for treatment of the Petitioner's GERD and is, therefore, not a covered benefit.

V. ORDER

The Director upholds BCBSM's 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.

Patrick M. McPharlin
Director

For the Director



Randall S. Gregg
Special Deputy Director