

**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. 150809-001**

**Blue Cross Blue Shield of Michigan,**  
**Respondents.**

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Issued and entered  
this 14<sup>th</sup> day of December 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

██████████ (Petitioner) was denied coverage for a surgical procedure by his health insurer, Blue Cross Blue Shield of Michigan (BCBSM).

On November 11, 2015, he filed a request with the Director of Insurance and Financial Services seeking an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 et seq. On November 9, 2015, after a preliminary review of the material submitted, the Director accepted the request.

The Petitioner receives group health care benefits through a plan underwritten by BCBSM. The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. The Director received BCBSM's response on November 23, 2015.

To address the medical issue, the case was assigned to an independent review organization which provided its recommendation to the Director on December 1, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner's health care benefits are described in BCBSM's *Community Blue Group Benefits Certificate SG*<sup>1</sup> (the certificate).

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<sup>1</sup> BCBSM form no. 457F, effective 01/14.

The Petitioner has gastroesophageal reflux disease (GERD). To treat his condition, his physician asked BCBSM to authorize a surgical procedure called “transoral incisionless fundoplication” (TIF). TIF is intended to correct an anatomic defect that causes GERD. BCBSM denied the request, saying the procedure is investigational for treating the Petitioner’s condition.

The Petitioner appealed the denial through BCBSM’s internal grievance process. At the conclusion of that process, BCBSM affirmed its decision in a final adverse determination dated September 28, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

### III. ISSUE

Did BCBSM correctly deny coverage for the transoral incisionless fundoplication procedure?

### IV. ANALYSIS

#### BCBSM’s Argument

In its final adverse determination to the Petitioner, BCBSM representatives explained:

. . . The Blue Cross Blue Shield Association (BCBSA) and the Blue Cross Blue Shield of Michigan / Blue Care Network (BCBSM/BCN) Joint Uniform Medical Policy Committee (JUMP) has determined that this surgical procedure is considered investigational. Investigational services are not a benefit under [the Petitioner’s] health care plan. Therefore, prior authorization cannot be approved.

\* \* \*

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

A board-certified M.D. in General Surgery reviewed your appeal and [the Petitioner’s] health care plan benefits for Blue Cross Blue Shield of Michigan (BCBSM) and determined the following:

The submitted documentation was reviewed and a managerial-level conference was conducted between me and [the Petitioner’s physician] to discuss this appeal case. Per the BCBSM medical policy and BCBSA medical policy titled "Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD)," this surgical procedure is considered investigational and / or experimental.

### Petitioner's Argument

The Petitioner's surgeon explained the reasons for the TIF procedure:

[The Petitioner] requires anti-reflux surgery and as a General Surgeon, I am best qualified to determine the best approach given my patient's needs. I have thoroughly examined this patient and fully understand his daily reflux. We have tried medical management with the use of Proton pump inhibitors (PPIs) without benefit. [He] has exhausted maximum medical management intervention.

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Specifically, my patient . . . has had symptomatic chronic gastroesophageal reflux for the past 10-12 years. His symptoms are not satisfactorily responsive to medical therapy as judged by multiple courses of PPIs which include Ranitidine and Protonix. My patient continues to experience breakthrough symptoms such as chronic hoarse voice, regurgitation, chest pain and he feels as though he has a tennis ball stuck in his throat. [He] has hiatal hernia less than or equal to 2cm. His quality of life has been and continues to be adversely affected by GERD. He is unable to obtain quality sleep because of his heartburn. He has changed his diet as recommended to no avail. He has difficulty swallowing and has a continuous gassy / bloated feeling. As you can see by the medical records included, this patient has had a 48 hour pH test, an EGD and a motility study. All of these diagnostic tools have overwhelmingly shown that [the Petitioner] has GERD and requires anti-reflux surgery.

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I have found that the transoral approach to fundoplication attains similar control of patient reported GERD symptoms without the common adverse post-op sequelae. Patient outcomes are similar with TIF and are comparable to those following laparoscopic fundoplication, but with reduced risk of iatrogenic visceral and vascular injuries, wound infection and incisional hernias. . . .

### Director's Review

BCBSM determined that the TIF the procedure is investigational. "Experimental treatment" is defined in the certificate (p. 148) 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 certificate (p. 130) also has this exclusion:

#### **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, except as explained under “Clinical Trials (Routine Patient Costs),” “Oncology Clinical Trials” in Section 3 and “Services That Are Payable” below. In addition, we do not pay for administrative costs related to experimental treatment or for research management.

The question of whether the TIF procedure is investigational 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 surgery, 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 transoral incisionless fundoplication is not experimental / investigational for treatment of the member’s condition.

**Rationale:**

\* \* \*

The member has a DeMeester score of 41 and is refractory to long-term proton pump inhibitory therapy as well as lifestyle modifications. The member has chosen a minimally invasive surgical solution, which has been endorsed by his surgeon. The member’s surgeon indicated that the member requires surgical repair in the form of a transoral incisionless fundoplication. The MAXIMUS physician consultant indicated that the member requires surgical therapy for his gastroesophageal reflux disease at this point. Transoral incisionless fundoplication has been given CPT codes and is approved by Medicare in certain jurisdictions. The physician consultant indicated that articles supporting the long-term safety and efficacy of this procedure were submitted in support of this request. The consultant also indicated that there is a consensus statement from the American College of General Surgeons in support of this procedure. The physician consultant explained that transoral incisionless fundoplication has gained accepted and is considered a standard of care. The consultant also explained that the medical necessity of this procedure for treatment of the member’s condition is established by the work-up documented in the case file, which demonstrated gastroesophageal reflux disease and a small hiatal hernia.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that transoral incisionless fundoplication is not experimental / investigational 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 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 the transoral incisionless fundoplication is not experimental or investigational and is therefore a covered benefit.

### V. ORDER

The Director reverses BCBSM's final adverse determination of September 28, 2015. BCBSM shall cover the Petitioner's transoral incisionless fundoplication within 60 days of the date of this Order, and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this Order.

To enforce this Order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, toll free 877-999-6442.

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 sixty days from the date of this Order in the circuit court for the 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:



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Randall S. Gregg  
Special Deputy Director