

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. 148598-001-SF

State of Michigan, Plan Sponsor

and

Blue Cross Blue Shield of Michigan, Plan Administrator
Respondents

Issued and entered
this ^{30th} day of July 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On June 30, 2015, ██████████, authorized representative of his patient ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review, appealing a claim denial issued by Blue Cross and Blue Shield of Michigan (BCBSM). BCBSM is 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. On July 8, 2015, after a preliminary review of the information submitted, the Director accepted the Petitioner's request for review.

The Petitioner's benefits are defined in BCBSM's *Your Benefit Guide State Health Plan PPO* and its *Community Blue Group Benefits Certificate ASC*. The Director notified BCBSM of the external review request and asked BCBSM to submit the information used to make its final adverse determination. BCBSM provided its response on July 10, 2015.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation on July 20, 2015.

II. FACTUAL BACKGROUND

The Petitioner has a history of severe and persistent asthma. His doctor recommended bronchial thermoplasty to treat his condition. BCBSM denied coverage, ruling that bronchial thermoplasty is investigational for the treatment of the Petitioner's condition.

The Petitioner appealed BCBSM's denial through its internal grievance process. BCBSM held a managerial level conference on May 7, 2015, and issued a final adverse determination May 13, 2015, maintaining its denial. The Petitioner now seeks review of that determination from the Director.

III. ISSUE

Did BCBSM correctly deny authorization for the Petitioner's requested bronchial thermoplasty?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination, BCBSM wrote:

The BCBSM/BCN Joint Uniform Medical Policy Committee has determined that these surgical procedures are considered investigational. Investigational services are not a benefit under [Petitioner's] health care plan. Therefore, prior authorization cannot be approved.

* * *

[Petitioner] is covered under *Community Blue Group Benefits Certificate ASC*.

As explained in **Section 6: General Conditions of Your Contract:**

Experimental Treatment, on page 127 of the certificate, it states that we do not pay for experimental treatment, including experimental drug, devices, or services. It further states that a treatment, including items and services maybe determined to be experimental when:

- Medical literature or clinical experience is inconclusive as to whether the service is safe or effective for treatment of any conditions;
- It has been shown to be safe and effective treatment for some conditions, but there is inadequate medical literature or clinical experience to supports its use in treating the patient's conditions;
- Medical literature or clinical experience has shown the service to be unsafe

or ineffective or treatment of any condition;

- There is a written experimental or investigational plan by the attending provider or another provider studying the same service;
- There is a written informed consent used by the treating provider in which the service is referred to as experimental or investigation or other than conventional or standard treatment; and
- There are other factors.

A board-certified D.O. in Internal Medicine reviewed your claim, your appeal, and your health care plan benefits for the Blue Cross Blue Shield of Michigan (BCBSM) and determined the following:

We have reviewed the appeal. On May 07, 2015, a managerial-level conference was held with [REDACTED] regarding patient and member, [Petitioner]. [REDACTED] was appealing the denial of bronchial thermoplasty (31660 and 31661), on [Petitioner] to treat his refractory asthma. [REDACTED] stated that [Petitioner] does improve with steroids but is concerned regarding the complications and side effects of long term systemic steroid use. He reported that there was strong data in support of bronchial thermoplasty in carefully selected patients. However, [REDACTED] reports that there are no current clinical trials that [Petitioner] could enroll in. I discussed the BCBSM Policy and the rationale for denial at this time. According to the current BCBSM medical policy "Bronchial Thermoplasty for Treatment of Asthma," bronchial thermoplasty for the treatment of asthma is experimental and/or investigational. This is because further clinical studies are needed to evaluate the benefits, safety, and long term health implications of these procedures. Therefore, these surgical procedures are not approved.

Petitioner's Argument

In a June 12, 2015 letter accompanying the request for an external review, Petitioner's physician wrote:

I disagree with the determination by BCBS Michigan pursuant to their letter dated May 13, 2015 I have prescribed the bronchial thermoplasty procedure to control [Petitioner's] severe and persistent asthma.

Bronchial thermoplasty (BT) is an innovative procedure for the treatment of severe persistent asthma in patients [REDACTED] years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta2-agonists. This treatment has been shown to significantly reduce health care utilization, presenting an opportunity to improve patient outcomes and quality of life while

reducing overall health care costs. Newly published data confirms that BT is very cost effective in these patients with poorly controlled, severe persistent asthma....

* * *

[Petitioner] is currently taking prednisone daily, Ventolin HFA, 2 puffs every 4 hours, Advair Diskus, 1 puff twice daily, Spiriva HandiHaler, and Singulair daily to control his severe persistent asthma. This medication represents maximum medical therapy for this patient based on current treatment guidelines.

[Petitioner] appears to be adherent to these prescribed controller medications, based on my assessments and those of the referring physician. Yet, my patient's severe persistent asthma is not well controlled. This is evidenced by his persistent symptoms of wheezing, cough, dyspnea, and chest tightness. We have managed, on relatively high doses of chronic prednisone, to improve his spirometry and symptoms somewhat however we would like to decrease his need for toxic medications and the potentially life-threatening side effects. Due to severe persistent asthma, [Petitioner] is currently unable to adequately carry out activities of daily living. If the bronchial thermoplasty treatment is not approved, his overall health and wellbeing are in jeopardy.

Bronchial thermoplasty, a non-drug treatment, is approved by the Food and Drug Administration (FDA) for the treatment of severe persistent asthma in patients, like [Petitioner], whose asthma is not well controlled with inhaled corticosteroids and long acting beta-agonists. Bronchial thermoplasty uses thermal energy to reduce the smooth muscle in the airway wall which is associated with airway constriction and resultant asthma exacerbations in patients with asthma. Bronchial thermoplasty was reviewed and approved through the most stringent FDA review process available for medical devices (i.e. the pre-market approval process).

* * *

I am submitting with this letter, [Petitioner's] medical record as well as a clinical summary document supporting the safety and effectiveness of bronchial thermoplasty. This procedure is medically necessary in order to adequately control [Petitioner's] asthma.

Director's Review

The *Community Blue* certificate, on page 142, defines experimental/investigational 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."

The question of whether bronchial thermoplasty is investigational or experimental for the

treatment of Petitioner's condition was presented to an independent review organization (IRO) to evaluate the requested treatment, as required by section 11(6) of the Patient's Right to Independent Review Act. The IRO reviewer is a physician in active practice who is certified by the American Board of Internal Medicine with a subspecialty in critical care medicine and pulmonary disease. The IRO reviewer's report included the following analysis and recommendation:

Bronchial thermoplasty has been Food and Drug Administration (FDA) approved for the treatment of asthma in the U.S.

The recent International European Respiratory Society (ERS)/American Thoracic Society (ATS) practice parameters on the treatment of severe asthma address the role of bronchial thermoplasty by recommending that "bronchial thermoplasty be performed in adults with severe asthma only in the context of an Institutional Review Board-approved independent systematic registry or a clinical study (strong recommendation, very low quality evidence). This is a strong recommendation, because of the very low confidence in the currently available estimates of effects of bronchial thermoplasty in patients with severe asthma. Both potential benefits and harms may be large and the long-term consequences of this new approach to asthma therapy utilizing an invasive physical intervention are unknown."...

The recent Cochrane review included randomized controlled clinical trials that compared bronchial thermoplasty versus any active control in adults with moderate or severe persistent asthma. The primary outcomes were quality of life, asthma exacerbations and adverse events. Included were three trials (429 participants) with differences in their design (two trials compared bronchial thermoplasty vs medical management and the other compared bronchial thermoplasty vs a sham intervention) and participant characteristics. "The pooled analysis showed improvement in quality of life at 12 months in participants who received bronchial thermoplasty that did not reach the threshold for clinical significance. Measures of symptom control showed no significant differences. The risk of bias for these outcomes was high because two of the studies did not have a sham intervention for the control group. The results from two trials showed a lower rate of exacerbation after 12 months of treatment for participants who underwent bronchial thermoplasty. The trial with sham intervention showed a significant reduction in the proportion of participants visiting the emergency department for respiratory symptoms. The trials showed no significant improvement in pulmonary function parameters." ...

It cannot be determined whether this enrollee's asthma phenotype would be expected to benefit from an intervention such as bronchial thermoplasty as compared to usual standard therapy. Further research should provide better

understanding of the mechanisms of action of bronchial thermoplasty, as well as its effect in different asthma phenotypes or in patients with worse lung function.”

The enrollee has severe steroid-dependent asthma. His medical therapy is in accordance with the usual stepped care approach to treatment established by the National Heart, Lung and Blood Institute (NHLBI) asthma treatment guidelines. The bronchial thermoplasty is considered to be experimental/investigational and therefore not medically necessary for the treatment of the enrollee’s condition.

It is the recommendation of this reviewer that denial of coverage issued by Blue Cross Blue Shield of Michigan...be upheld.

The Director is not required in all instances to accept the IRO’s recommendation. However, the IRO’s recommendation is afforded deference by the Director. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). 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. The Director can discern no reason why the IRO’s recommendation should be rejected in the present case. The Director finds that bronchial thermoplasty is investigational in the treatment of the Petitioner’s condition.

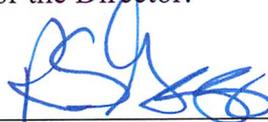
V. ORDER

The Director upholds Blue Cross Blue Shield of Michigan’s final adverse determination of May 13, 2015.

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 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

