

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. 147745-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 3rd day of June 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On May 5, 2015, ██████████ authorized representative of ██████████ (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.* On May 12, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a group plan that is underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are defined in the *MESSA Account-Based Choices ABC Plan 1 Coverage Guide*. 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 the material on May 20, 2015.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation on May 26, 2015.

II. FACTUAL BACKGROUND

The Petitioner has a history of severe persistent asthma. Her doctor recommended bronchial thermoplasty to treat her condition. The Petitioner requested that BCBSM provide coverage for the treatment. BCBSM denied the request, ruling that bronchial thermoplasty is investigational/experimental in the treatment of her condition.

The Petitioner appealed BCBSM's denial through its internal grievance process. BCBSM held a managerial level conference on March 3, 2015, and issued its final adverse determination March 5, 2015, maintaining its denial. The Petitioner now seeks review of that determination from the Director.

III. ISSUE

Was BCBSM correct in denying coverage for the Petitioner's bronchial thermoplasty?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination, BCBSM wrote:

You are covered under the *MESSA Account-Based Choices (ABC) Plan 1*. Page 45 of your *Plan Coverage Guide*, under subsection **Exclusions and Limitations**, explains that the following exclusion and limitation applies to the MESSA ABC Plan:

- Experimental treatment (including experimental drugs or devices) or services related to experimental treatment except as approved by the BCBSM or MESSA medical director. In addition, we do not pay for administrative costs related to experimental treatment or for research management.

A board-certified M.D. in General Surgery reviewed the submitted documentation and determined:

All of the documentation was reviewed for the 63 year old female patient. The provider is seeking preauthorization for Bronchial Thermoplasty as treatment for asthma. We are unable to approve the pre-authorization/payment, as the current BCBSM Medical Policy titled "Bronchial Thermoplasty for the Treatment of Asthma" indicates that the safety and effectiveness of Bronchial Thermoplasty for the treatment of asthma have not been established. Further studies are needed to evaluate the clinical utility, safety and long term health implications of this procedure. Therefore, Bronchial Thermoplasty for the treatment of asthma is experimental/investigational.

The BCBSM Medical Policy titled Bronchial Thermoplasty for the Treatment of Asthma explains:

The safety and effectiveness of Bronchial Thermoplasty for the treatment of asthma have not been established. Further studies are needed to

evaluation the clinical utility, safety and long term health implications for this procedure. Bronchial Thermoplasty for the treatment of asthma is experimental/investigational.

Therefore, because procedure codes 31660 and 31661 are considered experimental/investigational, our denial of prior authorization must be maintained. If you choose to receive the procedures, you will be responsible for the charges.

Petitioner's Argument

In a March 26, 2015 letter, Petitioner's physician wrote:

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 18 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 healthcare 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....

It should be noted that the Global Initiative for Asthma (GINA), a global network of asthma experts who make recommendations on strategies for asthma care, has just updated their asthma management strategy report, which now identifies BT as an add-on therapy option for selected patients who are at Step 5 and are still symptomatic.... The British Thoracic Society (BTS) also updated their asthma treatment guidelines and includes BT as an option for selected patients who have poorly controlled asthma despite maximal therapy (Step 4 or 5 of their guidelines). In addition, it should be noted, the American College of Chest Physicians (CHEST) issued the following statement on May 12, 2014:

CHEST believes that based on the strength of the clinical evidence, bronchial thermoplasty offers an important treatment option for adult patients with severe asthma who continue to be symptomatic despite maximal medical treatment, and therefore, should not be considered experimental. Randomized controlled clinical trials of bronchial thermoplasty for severe asthma have shown a reduction in the rate of severe exacerbations, emergency department visits, and days lost from school or work. Additionally, data published in December, 2013 demonstrates the persistence of the reduction in asthma symptoms achieved by bronchial thermoplasty for at least 5 years. CHEST has issued this statement because many of the currently published coverage policies and treatment guidelines were finalized prior to the publication of the five year follow-up data

from the Asthma in Research 2 (AIR2) study. As a result, bronchial thermoplasty is characterized as "experimental," or as requiring additional research in such coverage policies and guidelines. We believe that, given the extensive body of evidence demonstrating safety, effectiveness, and durability, bronchial thermoplasty is not experimental and should not be withheld from patients pending additional clinical trials.

* * *

[Petitioner] is currently taking albuterol, budesonide-formoterol, cetirizine, and montelukast to control her 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 her persistent symptoms of shortness of breath and wheezing without frequent use of her albuterol inhaler, which she requires daily and multiple times per day several days a week. Due to severe persistent asthma, her quality of life is not optimal. If the bronchial thermoplasty treatment is not approved, her condition is expected to deteriorate. Based on the fact that asthma is her only chronic illness and source of dyspnea, she is an ideal candidate for bronchial thermoplasty.

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. I am requesting authorization of all three sessions of bronchial thermoplasty....

Director's Review

To determine whether bronchial thermoplasty is investigational or experimental for the treatment of Petitioner's condition, the Director engaged 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 subspecialties in general internal medicine and pulmonary disease. The reviewer is an associate professor at a university school of medicine and is a Fellow of the American College of Chest Physicians. The IRO report included the following analysis and recommendation:

Reviewer's Decision and Principal Reasons for the Decision:

It is the determination of this reviewer that bronchial thermoplasty is currently considered experimental/investigational for the treatment of the enrollee's condition.

Clinical Rationale for the Decision:

Bronchial thermoplasty (BT) is a new technique proposed to improve control of moderate to severe asthma. It delivers thermal energy to the large airways during a bronchoscopy to decrease the amount of bronchial smooth muscle. Bronchial thermoplasty was approved by the Federal Drug Administration (FDA) on April 27, 2010 for the treatment of asthma. However, the medical or scientific evidence does not demonstrate that the expected benefits of bronchial thermoplasty are more likely to be beneficial to the enrollee than any available standard health care service.

[Summary of bronchial thermoplasty studies omitted.]

The National Institute for Health and Clinical Excellence...has issued a guidance concerning bronchial thermoplasty for severe asthma, stating the current evidence on the efficacy shows some improvement in symptoms and quality of life and a reduction in exacerbations and admission to the hospital. Evidence on safety is adequate in the short and medium term. More evidence is required on the safety of the procedure in the long term. Therefore, "this procedure should only be used with special arrangements for clinical governance, consent and audit or research." NICE encourages further research into bronchial thermoplasty for severe asthma; "research outcomes should include objective measurements of lung function, symptom control, medication requirements and quality of life with emphasis on long-term safety and efficacy outcomes."

According to Global Initiative for Asthma GINA guidelines, longer-term follow-up of larger number of control and active patients is needed to assess effectiveness of BT. Caution should be used in selecting patients for this procedure.

* * *

Based on the International European Respiratory Society and American Thoracic Society (ERS/ATS) guidelines published in February 2014, bronchial thermoplasty should be performed only in clinical trials or registry settings

because of very low confidence in available evidence on its effects in patients with severe asthma.

In conclusion, this enrollee suffers from severe persistent asthma. As discussed above, there is no convincing evidence that supports the long term efficacy and safety of bronchial thermoplasty in the treatment of asthma. Further studies are required to better define the role of this option in the treatment of asthma.

Therefore, the proposed bronchial thermoplasty is considered experimental/ investigational.

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, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that bronchial thermoplasty is investigational/experimental in the treatment of the Petitioner's condition.

V. ORDER

The Director upholds Blue Cross Blue Shield of Michigan's final adverse determination of March 5, 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