

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. 152432-001

Molina Healthcare of Michigan
Respondent

Issued and entered
this 30th day of March 2016
by **Randall S. Gregg**
Special Deputy Director

ORDER

I. BACKGROUND

On February 29, 2016, ██████████, on behalf of her ██████ son ██████████ (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.*

The Petitioner receives health care benefits through Molina Healthcare of Michigan, a health maintenance organization for Medicaid beneficiaries.

The Director notified Molina of the external review request and asked for the information used to make its final adverse determination. After a preliminary review of the information submitted, the Director accepted the request on March 7, 2016.

The medical issues in the case were analyzed by an independent review organization which provided its report and recommendation to the Director on March 21, 2016.

II. FACTUAL BACKGROUND

The Petitioner suffers from pulmonary problems. To treat his condition, his doctor prescribed a device known as a high frequency chest wall oscillation system. The device is also known by its commercial name, the Vest Airway Clearance System.

Molina denied coverage for the device. The Petitioner's mother appealed the denial through Molina's internal grievance process. At the conclusion of that process, on January 29, 2016, Molina issued a final adverse determination affirming its coverage denial. The Petitioner's mother now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did Molina correctly deny the Petitioner's request for coverage for the requested device?

IV. ANALYSIS

Respondent's Argument

Molina stated that its denial of coverage was based on criteria for high frequency chest wall oscillation devices detailed in the medical supplier provisions of the *Medicaid Provider Manual*.¹ In its final adverse determination, Molina stated that coverage for the device is only provided for individuals who have been diagnosed with cystic fibrosis. Molina wrote:

The documentation (clinical or office notes) that we received shows that the member has a history of respiratory infections and Atelectasis, however the notes do not show the member has Cystic Fibrosis.

Petitioner's Argument

In a letter submitted with the request for external review, a representative of the device manufacturer wrote:

Physicians prescribe The Vest System because of an identified need for secretion clearance. Bronchiectasis is a chronic illness which involves compromised mucociliary clearance, one of the underlying issues with pulmonary decline in patients with the inability to clear mucus from their airways. Stasis of secretions creates an environment conducive to bacterial colonization, exacerbations, and loss of pulmonary function secondary to permanent lung tissue damage. With recurrent infections and required antibiotic therapy, resistant pathogens become more prevalent, which leads to intravenous and inhaled antibiotics to effectively treat subsequent infections. The goal of aggressive airway clearance is prevention of recurrent infections and deterioration in pulmonary function associated with retention of secretions and mucus.

[Petitioner] is 14 years old, has bronchiectasis, asthma, tracheobronchitis and a history of Mycobacterium avium complex (MAC) and Pseudomonas pneumonia. He has experienced recurrent respiratory infections requiring use of antibiotics and a therapeutic bronchoscopy. Vest therapy, prescribed by his pulmonologist, has provided an effective method of airway clearance that is required to keep him healthy and prevent repeated infections, as well as hospitalizations....

Director's Review

Molina provides benefits for the requested device if the criteria in the *Medicaid Provider Manual* are met. The *Medicaid Provider Manual's* coverage for the requested device is in section 2.15, page 42, which provides:

1. The *Medicaid Provider Manual* provides guidance for all health insurance programs administered by the Michigan Department of Health and Human Services. The Petitioner's Molina plan is one such program.

2.15 HIGH FREQUENCY CHEST WALL OSCILLATION DEVICE

Definition

A high frequency chest wall oscillation (HFCWO) system is an airway clearance device consisting of an inflatable vest connected by two tubes to a small air-pulse generator that is easy to transport. The air-pulse generator rapidly inflates and deflates the vest, gently compressing and releasing the chest wall to create mini-coughs that dislodge mucus from the bronchial walls, increase mobilization, and facilitates it along toward central airways.

Standards of Coverage

A HFCWO system may be covered up to four months if both of the following apply:

- Diagnosis of Cystic Fibrosis, and
- All other treatment modalities have not been effective.

Documentation

Documentation must be less than 180 days old and include:

- Diagnosis pertaining to the need for this unit.
- Severity of condition (e.g., frequency of hospitalizations, pulmonary function tests, etc.).
- Current treatment modalities and others already tried.
- Plan of care by the attending Cystic Fibrosis (CF) Center specialist substantiating need for the device is required under the CSHCS Program.
- For continuation beyond the initial four months, the following information must be provided:
 - Documentation of client compliance through the review of equipment use logs; and
 - Medical statement from a CF Center Specialist substantiating the continued effectiveness of the vest is required under the CSHCS program.

In order to evaluate Molina's coverage decision and the standards upon which the decision was based, the Director assigned the medical issues to an independent medical review organization (IRO) as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO was asked to respond to the following questions:

- Does the Petitioner meet Molina's criteria for the air pulse generator system?
- Are these criteria the standard of care for the air pulse generator system?
- If Molina's criteria are not the standard of care, is the system medically necessary for the Petitioner?

The IRO reviewer is a physician in active practice who is board certified in internal medicine and pulmonology. The IRO reviewer's report contained the following analysis and recommendation:

The member had a CT scan of the chest performed on 3/18/15, which revealed possible aspergillus and acute/chronic peribronchial inflammation. Scattered atelectasis was noted....[T]here was no mention of diffuse bronchiectasis. The member had a listed diagnosis of bronchiectasis on the request for the Vest Airway Clearance System. This device is a high frequency chest wall oscillation device. The Health Plan allows the Vest only for patients with cystic fibrosis. The member does not have cystic fibrosis, and therefore, the Health Plan denied authorization for this device for him.

[N]ational Medicare criteria allow the Vest for patients with cystic fibrosis and diffuse bronchiectasis, which is the standard of care for coverage of this device. (National Medicare Criteria. 2008 Oct)...[T]herefore, the Health Plan's criteria for coverage for this device are not consistent with the standard of care....[T]here is no evidence that the Vest decreases the need for respiratory admission or decrease the number of days of hospitalization of a respiratory admission for the member's condition....[T]here was no documentation of failure of standard treatment in the information submitted for review....[T]he records provided for review do not document that the member has either cystic fibrosis or diffuse bronchiectasis. Therefore...based upon the information provided for review, the member does not meet the standard of care for coverage of this device.

Pursuant to the information set forth above and available documentation...the requested Air Pulse Generator System (the Vest Airway Clearance System) is not medically necessary 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 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. The Director can discern no reason why the IRO's recommendation should be rejected. Furthermore, it is not contrary to any provision of the Petitioner's certificate of coverage. See MCL 550.1911(15).

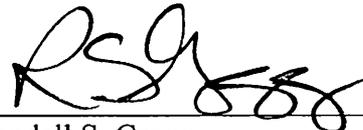
V. ORDER

The Director upholds Molina's final adverse determination of January 29, 2016.

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