

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. 145269-001

United Healthcare Insurance Company  
Respondent

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Issued and entered  
this 15<sup>th</sup> day of January 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On December 8, 2014, ██████████ (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.* After a preliminary review of the material received, the Director accepted the case on December 15, 2014.

The Petitioner receives medical benefits under a group plan underwritten by United Healthcare Insurance Company. The benefits are defined in the *United Healthcare Choice Plus* certificate of coverage. The Director notified United Healthcare of the request for an external review and asked for the information used in making its adverse determination. United Healthcare provided its response on January 6, 2014.

To address the medical issue in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on December 29, 2014.

**II. FACTUAL BACKGROUND**

The Petitioner has lymphedema (swelling) in both her lower legs. Her physician prescribed the Flexitouch pneumatic compression device and requested coverage from United Healthcare. The cost of the device is \$8,800.00.

United Healthcare denied coverage. The Petitioner appealed the denial through United Healthcare's internal grievance process. At the conclusion of that process, United Healthcare issued a final adverse determination dated October 7, 2014, affirming its benefit decision. The Petitioner now seeks a review of that adverse determination from the Director.

### III. ISSUE

Did United Healthcare correctly deny coverage for the Petitioner's proposed use of the Flexitouch pneumatic compression device?

### IV. ANALYSIS

#### Respondent's Argument

In its final adverse determination, United Healthcare explained its denial of coverage:

Your doctor has asked for insurance coverage for a special device called a FlexiTouch lymph drainage system. He has asked for this to reduce your leg swelling [lymphedema]. We looked at your doctor's notes. We looked at your health plan and medical policies. We looked at your case with a doctor who specializes in Thoracic and Cardiovascular Surgery. Use of a pump system as requested by your Nurse Practitioner would not be appropriate standard of care treatment for your condition. This is because your doctor has not supplied office notes that confirm you have not responded to regular treatment. Your doctor has not supplied doctor's notes that describe symptoms and objective findings. This includes measurements which establish the severity of your condition. There are no physician notes that give the reason the device is required. This would include the treatments which have been tried and failed. There are no physician notes that confirm the clinical response to an initial treatment with the device. The clinical response includes the change in pre-treatment measurements. It also includes the ability to tolerate the treatment session. It also includes your ability to apply the device for continued use in the home.

Your doctor has not supplied office notes that confirm you have a unique condition that would not be treatable with a lymph pump that is less advanced than the one ordered. Because of all of the above you do not meet your plan medical policy guidelines for medical necessity of this device. Services that are not medically necessary are not covered benefits under your plan.

#### Petitioner's Argument

The Petitioner's request for external review included an August 19, 2014 letter from her nurse practitioner, who wrote:

[Petitioner] attended physical therapy for her lymphedema and has been following the recommended home treatment program....She is very sensitive to heat which makes some conservative treatments difficult as the heat increases her swelling. Despite her efforts with conservative treatments and therapy, her swelling and symptoms persist. She is in need of effective treatment to manage her lymphedema to avoid further dangerous infections and worsening symptoms.

Lipcdema affects up to 11% of women. It occurs when fat is deposited abnormally beneath the skin, usually in the buttocks and legs. As the condition progresses, fat continues to accumulate and the lower body grows heavier. Over time, expanding fat cells block the vessels of the lymphatic system, which normally helps balance body fluid levels and protect against infection. This blockage prevents the proper drainage of lymph fluid, leading to a buildup of fluid called lymphedema.

I prescribed the Flexitouch pump for [Petitioner] as it is the only pump that applies the light pressures that she requires that will not exacerbate her symptoms or swelling. Standard pumps apply harsh constant pressures that patients with pain and skin sensitivity do not tolerate. In addition, standard pumps regularly produce additional swelling above and below the garments. This pump is essential to her lymphedema cure and will permit her to control her symptoms on her own at home.

In a letter dated June 20, 2014 the Petitioner's physical therapist stated:

At this time, I recommend the use of a sequential pneumatic compression machine to decrease the lymphedema into both legs and torso. She is not appropriate for standard wrapping since she does not have home support and cannot reach her legs to complete the wrapping. Her heat intolerance to environment in addition to garments and clothing is such that it provokes worsening swelling. Garments like Juxatafit are therefore not appropriate for her and neither is the Med Assist for the same reason.

### Director's Review

The *Choice Plus* certificate (pages 8 and 60) requires that any health service, supply or pharmaceutical product, in order to be covered, must be medically necessary. The Director, as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6), assigned the case to an independent medical review organization (IRO) to determine whether the Flexitouch pneumatic compression device is medically necessary in the treatment of the Petitioner's condition.

The IRO reviewer is a licensed physician in active practice who is board certified in physical medicine and rehabilitation and is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included the following analysis and recommendation:

[T]he evidence in the peer reviewed medical literature is insufficient to establish the marginal efficacy of the requested Flexitouch lymph drainage system to conventional lymphedema pumps. There is one published trial in the medical literature comparing the clinical effectiveness of this device to conventional maintenance therapy. This trial was a small, limited pilot study, which concluded that further investigations were warranted. (Wilburn O, et al. A pilot, prospective evaluation of a novel alternative for maintenance therapy of breast cancer-associated lymphedema. *BMC Cancer*. 2006 Mar;6:84.) A survey published in 2008 concluded that "patients using the Flexitouch system were satisfied with the device and perceived it to be beneficial in the management of their lymphedema." (Ridner SH, et al. Home-based lymphedema treatment in patients with cancer-related lymphedema on noncancer-related lymphedema. *Oncol Nurs Forum*. 2008 Jul;35(4):671-80.) It should be noted that there was no control group in this survey. There was a case series of two subjects published in 2009 with the assistance of the Flexitouch device manufacturer (Tactile Systems). (Cannon S. Pneumatic compression devices for in-home management of lymphedema: two case reports. *Cases J*. 2009 Mar;2:6625.) Another study published in 2010 also indicated that future clinical trials were warranted. (Adams KE, et al. Direct evidence of lymphatic function improvement after advance pneumatic compression device treatment of lymphedema. *Biomedical Optics Express*. 2010 Aug;1(1).) The physician consultant explained that there are other case studies and case service, but no high grade trials.

[O]verall, the published medical literature to date has not established the marginal efficacy of the device in question over conventional devices. The National Institutes of Health database at [clinicaltrials.gov](http://clinicaltrials.gov) indicates that there is a study in progress with an estimated enrollment of 200 subjects entitled "Lymphedema Prophylaxis in Breast Cancer Survivors Who Show Early Evidence of High-risk Status". (ClinicalTrials.gov identifier: NCT00383500)...The estimated study completion date is May 2015...[T]his study is consistent with either a phase IIB or phase III clinical trial...The specific device at issue is still investigational, especially with respect to efficacy over standard therapy...[W]hile the member has clinically significant lymphedema and requires pneumatic compression, the efficacy of the requested device has not been established over other standard pneumatic compression device options.

Pursuant to the information set forth above and available documentation...the requested Flexitouch lymph drainage system is 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 analysis is based on extensive experience, expertise, and professional judgment and is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15). The Director can discern no reason why the IRO's recommendation should be rejected in the present case.

The Director finds that the Flexitouch pneumatic compression device is not medically necessary for treatment of the Petitioner's condition and is, therefore, not a covered benefit under the certificate.

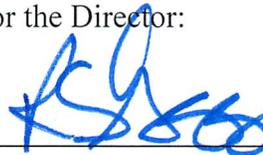
#### V. ORDER

The Director upholds United Healthcare Insurance Company's October 7, 2014 final adverse determination. United Healthcare is not required to provide coverage for the Flexitouch pneumatic compression device.

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.

Annette E. Flood  
Director

For the Director:



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Randall S. Gregg  
Special Deputy Director