

STATE OF MICHIGAN
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES
Before the Director of Insurance and Financial Services

In the matter of:

██████████,
Petitioner,

v

HealthPlus of Michigan, Inc.,
Respondent.

File No. 146932-001

Issued and entered
this 28th day of April 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On March 23, 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.*

The Petitioner receives group health care benefits from HealthPlus of Michigan, Inc. (HealthPlus), a health maintenance organization. The Director notified HealthPlus of the external review request and asked for the information it used to make its final adverse determination. HealthPlus responded on March 26, 2015. On March 30, 2015, after a preliminary review of the material submitted, the Director accepted the request.

This case involves medical issues so the Director assigned it to an independent review organization which submitted its recommendation on April 17, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in the HealthPlus *Group Subscriber Contract* (the contract)

On April 28, 2014, the Petitioner was taken by ambulance to the emergency department of ██████████. She was admitted and it was determined she had severe coronary artery

disease. She was discharged on April 30, 2014, with a Zoll LifeVest, a wearable automatic cardiac defibrillator.

Zoll, the device's manufacturer, asked HealthPlus to cover the rental of the LifeVest for the period from May 1 through June 3, 2014. HealthPlus denied the request, saying the Petitioner did not meet its criteria for coverage.

The Petitioner appealed the denial through HealthPlus's internal grievance process. At the conclusion of that process HealthPlus maintained its denial and issued a final adverse determination letter dated January 21, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did HealthPlus properly deny coverage for the LifeVest?

IV. ANALYSIS

Petitioner's Argument

In a January 15, 2015, letter that was submitted for the external review, the Petitioner's authorized representative explained why the life vest was medically necessary:

We received a denial . . . to our preapproval request . . . for the LifeVest. . . . The denial letters state the LifeVest is considered not medically necessary and therefore is not a covered benefit under the member's plan. We disagree with this decision. . . .

[The Petitioner] is a ■ year old woman with a family history of heart disease who presented to the hospital with syncope¹ and was found to have a non-ST elevated myocardial infarction. She was admitted to the hospital and underwent an Echocardiogram and a cardiac catheterization. Her Ejection Fraction (EF) was noted to be 40% with anterior apical dyskinesis and she received an angioplasty with stent to the LAD. She was then discharged to home with the LifeVest for protection from sudden cardiac death while on optimal medical therapy.

* * *

Patients with a low ejection fraction are at high risk for ventricular arrhythmias. A WCD is appropriate for patients in this specific situation and the clinical rationale is also compatible with AHA/ACC/ ESC Guidelines on sudden death

¹ A temporary loss of consciousness; fainting or passing out.

prevention. *An Implantable Device (ICD) was CONTRAINDICATED at the time of discharge from the hospital because the patient was status post PCI.*

Nothing about this case suggests that the prescribed use of the WCD is investigational, as the LifeVest is FDA approved and it is ideal for a temporary need as in this case. Ultimately, the patient's Ejection Fraction improved on medical therapy, while being protected from sudden cardiac death by the LifeVest (WCD), and she ended use on 06/03/14. [She] was protected by the WCD from the time period of 05/01/14 to 06/03/14.

Patients with a myocardial infarction and a low ejection fraction (EF) are well known to have a high mortality rate and the first month after an infarction carries the highest mortality, of which 50% is generally considered sudden death. The MADIT II trial established implantable defibrillators (AICD) as a valuable treatment for reducing the mortality in this patient population. AICD's are generally not implanted under MADIT II criteria in patients with acute infarctions and/or patients who are candidates for revascularization because the EF may change as the myocardium heals. Furthermore, the DINAMIT study showed AICD's did not improve the survival when implanted immediately after an infarction. High-risk sudden death patients who do not receive an implantable defibrillator rely on community emergency services for resuscitation.

Community resuscitation, which depends on bystander observing the patient's collapse, has a success rate less than 10% in most communities. In contrast, wearable defibrillators have a high rate of success when used consistently. In FDA approval trial of the LifeVest wearable defibrillator, the resuscitation success rate was 75% while the device was worn. The FDA approval trial used patients groups specifically restricted from ICD use due to temporary SCAS risks or due to delays in receiving an AICD (such as before CABG surgery). Over one third of the patients recruited for the study were either immediately after a myocardial infarction or after CABG surgery, with evidence of ventricular dysfunction.

* * *

Based on the information submitted in this External Appeal Member Level, we are requesting Michigan Department of Insurance and Financial Services to overturn the denials for dates of service 05/01/14 and 06/01/14 and to approve for payment. Additionally, we are requesting an in-network exception due to ZOLL is the sole provider and manufacturer of the LifeVest worldwide.

Respondent's Argument

In its final adverse determination, HealthPlus's appeals committee told the Petitioner's authorized representative:

. . . It was determined by the Grievance Appeal Committee to uphold the previous denial.

This decision is based on the fact that pursuant to **Section I - Covered Services**, *Only services that are Medically Necessary according to generally-accepted standards of practice as determined by an HPM Medical/Director are Covered Services under this Rider*. Documentation submitted by you and the ordering cardiologist . . . did not establish medical necessity as set forth in HealthPlus of Michigan's Reference & Control Operational Guideline (R&C). Because [the Petitioner] did not meet medical necessity, as set forth in the R&C guidelines, the wearable automatic cardiac defibrillator (life vest) is a non-covered benefit under the terms of her contract. [The Petitioner's] cardiologist . . . concurred that [she] did not need the life vest. As an explanation, the physician member of the Grievance Appeal Committee reached out, spoke directly to [the cardiologist] and additional medical records were obtained. [The cardiologist's] testimony and additional medical records did not establish member had met any one of the R&C criterion.

Director's Review

HealthPlus will cover a wearable automatic cardiac defibrillator if the criteria of its medical policy are met. Its Reference & Control Operational Guideline title "Wearable Automatic Cardiac Defibrillator" says:

The wearable automatic cardiac defibrillator is a covered benefit when one of the following criteria is met:

1. A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an electrophysiologic (EP) study, but may not be due to a transient or reversible cause and not occur during the first 48 hours of an acute myocardial infarction, or
2. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy, or
3. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular fraction less than or equal to 0.35, or
4. A previously implanted defibrillator now requires explanation.

For all members, the wearable automatic cardiac defibrillator requires HealthPlus Plan Medical Director approval.

The question of whether the Petitioner met the criteria for coverage, i.e., whether the life vest was medically necessary to treat her condition, was presented to an independent review organization (IRO) for a recommendation 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 internal medicine and cardiology, has been in practice for more than 10 years, and is familiar with the medical management of patients with the member's condition. The IRO report included the following analysis and recommendation:

Based on the documentation provided, the member presented with syncope and acute myocardial infarction. The cause of the syncope was not documented. The MAXIMUS physician consultant explained that even if the syncope were due to ventricular arrhythmias, these are generally not predictive of subsequent sudden cardiac arrest when they occur during the first 24 to 48 hours of an acute myocardial infarction. There is no documentation of dysrhythmias beyond 24 hours from the acute infarction. The physician consultant explained that although ejection fraction is predictive of subsequent sudden cardiac death from arrhythmias, the ejection fraction in this member's case was only mildly reduced at 40%. The consultant also explained that there was potential for recover[y] of left ventricular function as there was no indication for immediate placement of a defibrillator such as sustained or inducible ventricular tachycardia, syncope or aborted sudden cardiac arrest beyond 24 to 48 hours from the acute myocardial infarction. Placement of a prophylactic defibrillator is not recommended until a period of time of greater than 90 days where continued left ventricular dysfunction with an ejection fraction of less than or equal to 35% is documented to persist in spite of appropriate treatment. The physician consultant explained that the use of a wearable or implantable prophylactic defibrillator before this time has not been demonstrated to improve outcomes. For example, studies assessing efficacy of prophylactic defibrillators early after diagnosis of myocardial infarction and reduced ejection fraction of less than or equal to 35% before ventricular function has had a chance to recover have not demonstrated improved outcome. Studies evaluating wearable defibrillators during periods of increased risk where criteria for implantable defibrillators have not yet been met are largely comprised of registry data on patients with lower ejection fractions of less than 35% without adequate control groups. The "Vest Prevention of Early Sudden Death Trial (NCT01446965)" and "Vest/Predicts Trial (NCT00628966)" are two randomized trials currently enrolling patients to help address this question and the results of these trials are not yet available. The consultant explained that at this time, a prophylactic wearable external defibrillator would only be indicated if accepted criteria for an implantable defibrillator were met

and the implantable defibrillator could not be placed, placement needed to be significantly delayed or required explanation. The physician consultant indicated that the medical necessity for a prophylactic wearable defibrillator in the circumstances present in this member's case has not yet been demonstrated by existing scientific literature.

Pursuant to the information set forth above and available documentation, the MAXUMUS physician consultant determined that the wearable external defibrillator that the member received was not medically necessary for treatment of her 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. 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, finds that a wearable external defibrillator was not medically necessary to treat the Petitioner's condition.

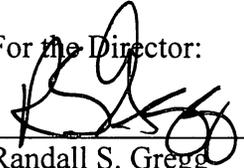
V. ORDER

The Director upholds HealthPlus's January 21, 2015, final adverse determination.

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 Director of Insurance and Financial Services, Health Care Appeals Section, Post Office Box 30220, Lansing, MI 48909-7720.

Annette E. Flood
Director

For the Director:


Randall S. Gregg
Special Deputy Director