STATE OF FLORIDA
DEPARTMENT OF CHILDREN AND FAMILIES
OFFICE OF APPEAL HEARINGS

[redacted]

APPEAL NO. 15F-09843

PETITIONER,

Vs.

AGENCY FOR HEALTH CARE ADMINISTRATION
CIRCUIT: 04 DUVAL
UNIT: AHCA

RESPONDENT.
_____/

FINAL ORDER

Pursuant to notice, the undersigned convened a telephonic administrative hearing in the above matter on January 14, 2016 at 11:06 a.m.

APPEARANCES

For the Petitioner: [redacted]
Appeals Coordinator
[redacted]

For the Respondent: Selwyn Gossett
Medical/Health Care Program Analyst

STATEMENT OF ISSUE

Whether respondent's denial of a wearable cardioverter defibrillator (LifeVest) was proper. The burden of proof was assigned to the petitioner.

PRELIMINARY STATEMENT

Petitioner was not present. A written authorization appointing [redacted] as petitioner's representative was provided. Petitioner's exhibit "1" was entered into evidence.

Mr. Gossett appeared both as a witness and representative for the respondent. Present from Sunshine Health were Tracy Thomas, Appeals Coordinator II and Dr. David Gilchrist, Medical Director. Respondent's exhibit "1" was entered into evidence.

The record was held open through January 21, 2016 for respondent to provide relevant InterQual Criteria and for the petitioner to provided relevant CMS National Coverage Policy.

Information was timely received from each party and entered as petitioner's exhibit "2" and respondent's exhibit "2".

FINDINGS OF FACT

Based on the oral and documentary evidence presented at the final hearing and on the entire record of this proceeding, the following Findings of Fact are made:

1. Petitioner's date of birth is [redacted] She is diagnosed with [redacted]

2. Petitioner was Medicaid eligible at all times relevant to this proceeding.

3. Petitioner's Medicaid services are provided through respondent's Statewide Medicaid Managed Care Program; specifically, the Managed Medical Assistance Program.

4. Sunshine Health is the managed care entity which provides petitioner's medical services.

5. A LifeVest is one of two types of cardioverter defibrillators. An implantable cardioverter defibrillator (ICD) is surgically inserted into the recipient's chest. A LifeVest is worn outside the body. Each type provides continuous monitoring of heart rhythms. When necessary, each provides an electrical shock directly to the heart.

6. A LifeVest is, in most instances, provided on a rental basis.

7. The medical coding for a Life Vest is K0606.

8. Due to abdominal pain, on July 18, 2015 petitioner was evaluated in the emergency room at Memorial Hospital of Jacksonville. On that day, petitioner was admitted into the hospital.

9. After admission, testing revealed a diseased gallbladder. On July 22, 2015 a [redacted] was performed.

10. Cardiac testing was also performed. Petitioner was diagnosed with [redacted] The test report stated, in part:

[redacted]

11. No comorbid conditions, such as [redacted]; [redacted]; or [redacted], were noted.

12. On July 25, 2015 petitioner was discharged from the hospital. At discharge she was provided with a LifeVest. Petitioner was to be re-evaluated in 90 days. If her EF remained low, and ICD would be implanted. In such an instance, the Life Vest would be returned.

13. Petitioner received, at an unspecified date, an ICD.

[1] Ejection Fraction. An EF is considered when evaluating the hearts blood pumping efficiency. An EF of less than 35% is considered to be abnormal.

14. On July 30, 2015 Sunshine Health received an authorization request for the Life Vest (K0606).

15. Using InterQual Criteria for a LifeVest, a Sunshine Health physician reviewed submitted information.

16. InterQual Criteria is a nationally recognized standard for medical treatment. The criteria is used by hospitals and insurance companies to determine the appropriate level of medical care.

17. On July 31, 2015 a Notice of Action was issued by Sunshine Health denying the request for a LifeVest. A LifeVest was not demonstrated to be medically necessary.

18. Petitioner's representative thereafter requested an internal appeal. [redacted] wrote, in part:

> According to CMS[2] National Coverage Policy, [redacted] meets criteria #3 for diagnosis [redacted] CMS a nationally recognized resource, does not allow for ICD placement within several months of the diagnosis because of the possibility that the patients LV function may improve enough that the ICD is no longer indicated. However, the patient remains at risk for sudden death during that time period. The Life Vest's role is to provide function as an external ICD during the waiting period. This is the standard of care for most insurance companies and physicians.

19. [redacted] who was not the initial physician reviewer, completed a second analysis of submitted information. [redacted] is board certified in both emergency and internal medicine.

20. On September 4, 2015 a Notice of Action was issued upholding the original denial. The notice stated, in part:

[2] Centers for Medicare & Medicaid Services.

> There is no history of cardiac arrest (sudden loss of heart function) without concomitant myocardial infarction (heart attack), ventricular arrhythmia (irregular heart beat), familial (family history) or congenital (from birth) conditions with high risk of life threatening ventricular tachycardia/arrhythmia, or prior implantable cardioverter defibrillator (automatic internal heart defibrillator) removal without immediate replacement. There is no contraindication (a reason that something should not be done) to the implantation of a cardioverter-defibrillator (automatic internal heart defibrillator), such as a heart attack less than 40 days ago or a coronary (heart) intervention such as a stent or bypass surgery within the past 12 weeks.

21. On November 25, 2015 the Office of Appeal Hearings timely received petitioner's request for a fair hearing.

22. [redacted] has 25 years of experience in the health care industry. A sizeable portion of her career has been in claims and benefits.

23. Post hearing, CMS material was presented. The Coverage Guidance for a wearable (K0606) states the DME is covered for Medicare beneficiaries if they meet one of the four criteria. Criterion # 3 is: "Either documented [redacted] or [redacted] and a [redacted]

24. Respondent asserts the prior authorization process was not followed. A Life Vest should have been requested prior to hospital discharge. Respondent asserts, based on InterQual Guidelines, the LifeVest would have been denied at that time. As opposed to a LifeVest, an ICD should have been implanted during the initial hospitalization period.

CONCLUSIONS OF LAW

25. By agreement between the Agency for Health Care Administration (AHCA) and the Department of Children and Families, AHCA has conveyed jurisdiction to the

Office of Appeal Hearings to conduct this hearing pursuant to § 120.80, Fla. Stat.

26. This hearing was held as a *de novo* proceeding pursuant to Fla. Admin. Code R. 65-2.056.

27. The standard of proof in an administrative hearing is by a preponderance of the evidence. The preponderance of the evidence standard requires proof by "the greater weight of the evidence," (Black's Law Dictionary at 1201, 7th Ed.).

28. Section 409.973, Fla. Stat. addresses the minimum benefits provided under Medicaid managed care plans and states, in part:

> (1) MINIMUM BENEFITS. – Managed care plans shall cover, at a minimum, the following services:
> (p) Medical supplies …

29. Fla. Admin. Code R. 59G-1010(163) defines medical supplies as "medical or surgical items that are consumable, expendable, disposable or non-durable and that are used for treatment or diagnosis of a patient's specific illness, injury, or condition…"

30. The Findings of Fact establish a LifeVest is consider to be Durable Medical Equipment. As such, respondents Durable Medical Equipment/Medical Supply Services Coverage and Limitations Handbook (DME Handbook) is relevant to this proceeding. The DME Handbook has been promulgated into rule by Fla. Admin. Code R. 59G-4.070.

31. The DME Handbook requires medical supplies provided to a Medicaid recipient be medically necessary.

32. Florida Administrative Code Rule 59G-1.010(166) defines medical necessity, as follows:

> "Medically necessary" or "medical necessity" means that the medical or allied care, goods, or services furnished or ordered must:
>
> (a) Meet the following conditions:
>
> 1. Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
> 2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
> 3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
> 4. Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available; statewide; and
> 5. Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider. …
> …
> (c) The fact that a provider has prescribed, recommended, or approved medical or allied care, goods, or services does not, in itself, make such care, goods or services medically necessary or a medical necessity or a covered service.

33. In this instant appeal, conflicting guidelines for the LifeVest exist.

34. It is noted the CMS Coverage Guidance for a LifeVest focuses on Medicare beneficiaries. It was not established this policy is mandatory for Florida Medicaid recipients. In particular, for those individuals over the age of 21.

35. Petitioner's ejection fraction is noted. Her cardiac status, however, did not warrant stents. Additionally, there is no evidence of a recent heart attack or irregular heartbeat.

36. Compelling evidence was not provided why an ICD should not have been initially implanted.

37. After weighing the testimony and documentary evidence of both parties, the undersigned assigns more weight to respondent's arguments.

38. Petitioner has not established, in a preponderant manner, that respondent's action in this matter was improper. The greater weight of evidence does not establish the following conditions of medical necessity have been satisfied:

> 2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
> 3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;
> 4. Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available; statewide;

DECISION

Based upon the foregoing Findings of Fact and Principles of Law, petitioner's appeal is denied.

NOTICE OF RIGHT TO APPEAL

This decision is final and binding on the part of the agency. If the petitioner disagrees with this decision, the petitioner may seek a judicial review. To begin the judicial review, the petitioner must file one copy of a "Notice of Appeal" with the Agency Clerk, Agency for Health Care Administration, 2727 Mahan Drive, Tallahassee, FL 32308-5403. The petitioner must also file another copy of the "Notice of Appeal" with the appropriate District Court of Appeal. The Notices must be filed within thirty (30) days of the date stamped on the first page of the final order. The petitioner must either pay the court fees required by law or seek an order of indigency to waive those fees. The petitioner is responsible for any financial obligations incurred as the agency has no funds to assist in this review.

DONE and ORDERED this 01 day of February, 2016, in Tallahassee, Florida.

Frank Houston

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Hearing Officer
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