[redacted]
MI [redacted]

Date Mailed: May 27, 2021
MOAHR Docket No.: 21-002016
Agency No.: [redacted]
Petitioner: [redacted]

ADMINISTRATIVE LAW JUDGE: Corey Arendt

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and 42 CFR 431.200 *et seq.,* upon the Petitioner's request for a hearing.

After due notice, a hearing was held on May 25, 2021. [redacted], Nurse Practitioner, appeared on behalf of Petitioner. Melissa Sweet, Appeals Coordinator, appeared on behalf of Respondent, McLaren (Department). Dr. Dennis Perry, M.D., appeared as a witness for the Department.

Exhibits:

Petitioner	None
Department	A. Hearing Summary B. Hearing Summary Addendum

ISSUE

Did the Department properly deny Petitioner's prior authorization request for a CardioMEMS implantable hemodynamic monitor?

FINDINGS OF FACT

The Administrative Law Judge, based upon the competent, material, and substantial evidence on the whole record, finds as material fact:

1. Petitioner is a Medicaid beneficiary, born [redacted] 1989, who is enrolled with the Department. Petitioner has been diagnosed with chronic systolic heart failure with history of late presenting MI with large myocardial insult, coronary artery disease status post stenting of the left anterior descending artery as well as the diagonal branch. (Exhibit A, p 23; Testimony.)

2. On or around February 2, 2021, Bay Heart & Vascular, submitted to the

Department, a request for CardioMEMS implantable hemodynamic monitor for Petitioner. (Exhibit A, pp 20-21; Testimony.)

3. On February 15, 2021, the Department sent Petitioner a notice of denial. The notice indicated Petitioner's request for a CardioMEMS implantable hemodynamic monitor was denied. The notice indicated the denial was the result of the device not being a covered benefit per the Department's certificate of coverage in that Medicaid does not cover experimental, investigational, or unproven services. (Exhibit A, p 62; Testimony.)

4. On March 5, 2021, Petitioner sent the Department a local level appeal. Exhibit A, pp 8-15; Testimony.)

5. After receiving the March 5, 2021 appeal, the Department sent the request and file to a third party (Advanced Medical Review) to review. (Testimony.)

6. On April 13, 2021, Advanced Medical Review sent the department a document indicting the CardioMEMS implantable hemodynamic monitor was not medically necessary as it is investigational for heart failure and all other indications. (Exhibit A, pp 147-149.)

7. On April 20, 2021, the Department sent Petitioner a Notice of Internal Appeal Decision. The notice indicated Petitioner's appeal was denied based on Apollo guidelines in that the device being requested is investigational for heart failure and all other indications. (Exhibit A, pp 185-195.)

8. On April 27, 2021, the Michigan Office of Administrative Hearings and Rules, received from Petitioner, a request for hearing.

9. On May 21, 2021, the Department sent the request for services and additional information provided with the April 27, 2021 request for hearing to Advanced Medical Review for a second review. (Exhibit B, p 1; Testimony.)

10. On May 24, 2021, Advanced Medical Review issued a Peer Reviewer Final Report. The report indicated the CardioMEMS device was not medically necessary as the monitor is experimental investigational for heart failure and all other indications. (Exhibit B, p 2; Testimony.)

11. In 2014, the Food and Drug Administration, approved the use of the CardioMEMS implantable hemodynamic monitor. (Testimony.)

12. The Center for Medicare and Medicaid Services (CMS) has approved the CardioMEMS device. (Testimony.)

13. Michigan Medicaid has billing codes for the CardioMEMS device.

(Testimony.)

CONCLUSIONS OF LAW

The Medical Assistance Program is established pursuant to Title XIX of the Social Security Act and is implemented by Title 42 of the Code of Federal Regulations (CFR). It is administered in accordance with state statutes, the Social Welfare Act, the Administrative Code, and the State Plan under Title XIX of the Social Security Act Medical Assistance Program.

In 1997, the Department received approval from the Health Care Financing Administration, U.S. Department of Health and Human Services, allowing Michigan to restrict Medicaid beneficiaries' choice to obtain medical services only from specified Medicaid Health Plans. The Respondent is one of those MHPs and, as provided in the Medicaid Provider Manual (MPM), is responsible for providing covered services pursuant to its contract with the Department:

> **SECTION 1 – GENERAL INFORMATION**
>
> The Michigan Department of Health and Human Services (MDHHS) contracts with Medicaid Health Plans (MHPs), selected through a competitive bid process, to provide services to Medicaid beneficiaries. The selection process is described in a Request for Proposal (RFP) released by the Office of Purchasing, Michigan Department of Technology, Management & Budget. The MHP contract, referred to in this chapter as the Contract, specifies the beneficiaries to be served, scope of the benefits, and contract provisions with which the MHP must comply. Nothing in this chapter should be construed as requiring MHPs to cover services that are not included in the Contract. A copy of the MHP contract is available on the MDHHS website. (Refer to the Directory Appendix for website information.)
>
> MHPs must operate consistently with all applicable published Medicaid coverage and limitation policies. (Refer to the General Information for Providers and the Beneficiary Eligibility chapters of this manual for additional information.) Although MHPs must provide the full range of covered services listed below, MHPs may also choose to provide services over and above those specified. MHPs are allowed to develop prior authorization requirements and utilization management and review criteria that differ from Medicaid requirements. The following subsections describe covered services, excluded services, and prohibited services as set forth in the Contract.

****

1.3 SERVICES THAT MHPS ARE PROHIBITED FROM COVERING

****

- Experimental/Investigational drugs, procedures or equipment;[1]

****

Pursuant to the above policy and its contract with the Department of Health and Human Services, the Department, developed prior authorization requirements and utilization management and review criteria. Those criteria can be found in the Department's certificate of coverage.[2]

Pursuant to the above policies, the Department denied Petitioner's prior authorization request. The Department argued the device and usage was experimental and or investigational. However, they could not explain how Michigan Medicaid had a billing code for the device and usage. Medicare and Medicaid have explicit rules that forbid Medicare and Medicaid payments being for experimental or investigational drugs, procedures, or equipment. If the device is as alleged by the Department to be experimental or investigational, then Medicare and Medicaid WOULD NOT PERMIT payments to be made.

For these reasons, I find the Petitioner to have met their burden of proof in showing the Department did not follow the applicable laws and policies in denying the request for the CardioMEMS device. This order is not to say the device is or is not experimental or investigational in nature. Rather, it is to indicate the Department has not shown enough to establish that the device is experimental or investigational in nature.

As such, the Department's decision is reversed.

[1] Medicaid Provider Manual, Medicaid Health Plans, October 1, 2020, pp 1, 4.
[2] Exhibit A, p 171.

DECISION AND ORDER

The Administrative Law Judge, based on the above findings of fact and conclusions of law, decides that the Department improperly denied the prior authorization request for a CardioMEMS device.

IT IS THEREFORE ORDERED that:

The Department's decision is REVERSED.

The Department is ordered to initiate the reprocessing and review of Petitioner's request for a CardioMEMS device.

CA/dh

Corey Arendt
Administrative Law Judge
for Elizabeth Hertel, Director
Department of Health and Human Services

NOTICE OF APPEAL: A party may appeal this Order in circuit court within 30 days of the receipt date. A copy of the circuit court appeal must be filed with the Michigan Office of Administrative Hearings and Rules (MOAHR).

A party may request a rehearing or reconsideration of this Order if the request is received by MOAHR within 30 days of the date the Order was issued. The party requesting a rehearing or reconsideration must provide the specific reasons for the request. MOAHR will not review any response to a request for rehearing/reconsideration.

A written request may be mailed or faxed to MOAHR. If submitted by fax, the written request must be faxed to (517) 763-0155; Attention: MOAHR Rehearing/Reconsideration Request.

If submitted by mail, the written request must be addressed as follows:

Michigan Office of Administrative Hearings and Rules
Reconsideration/Rehearing Request
P.O. Box 30763
Lansing, Michigan 48909-8139

DHHS -Dept Contact	Managed Care Plan Division CCC, 7th Floor Lansing, MI 48919
Authorized Hearing Rep.	[redacted] MI
Petitioner	[redacted] MI
Community Health Rep	McLaren Health Plan G 3245 Beecher Rd. Suite 200 Flint, MI 48532
Authorized Hearing Rep.	[redacted] MI