[redacted]
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Date Mailed: April 26, 2023
MOAHR Docket No.: 23-001478
Agency No.: [redacted]
Petitioner: [redacted]

ADMINISTRATIVE LAW JUDGE: Steven Kibit

DECISION AND ORDER

This matter is before the undersigned Administrative Law Judge pursuant to MCL 400.9 and upon Petitioner's request for a hearing.

After due notice, a telephone hearing was held on April 19, 2023. Dr. Sanjay Patra, M.D., appeared and testified on Petitioner's behalf. Petitioner also testified on her own behalf. Melissa Sweet, Appeals Coordinator, represented McLaren Health Plan, the Respondent Medicaid Health Plan (MHP). Dr. Dennis Perry, Chief Medical Officer, testified as a witness for Respondent.

During the hearing, the following exhibits were admitted into the record without objection:

Exhibit A:	Request for Hearing
Exhibit B:	Internal Appeal Request
Exhibit C:	Initial Request
Exhibit D:	Initial Denial - Member
Exhibit E:	Initial Denial - Provider
Exhibit F:	InterQual Coverage Criteria
Exhibit G:	MLS Report
Exhibit H:	Certificate of Coverage
Exhibit I:	Appeal Determination Letter

ISSUE

Did Respondent properly deny Petitioner's request for a responsive intracranial neurostimulator?

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 who is enrolled in the Respondent MHP. (Exhibit C, page 1).

2. On or about February 15, 2023, Respondent received a prior authorization request for a responsive intracranial neurostimulator submitted on Petitioner's behalf by her doctor. (Exhibit C).

3. In part, that request indicated that Petitioner suffers from seizures and has been diagnosed with generalized epilepsy. (Exhibit C, pages 4-5; Testimony of Petitioner's representative).

4. On February 28, 2023, Respondent sent Petitioner and Petitioner's doctor written notices that the prior authorization request had been denied. (Exhibit D; Exhibit E).

5. With respect to the reason for the denial, the notice to Petitioner stated:

> This communication is in response to a request for authorization for a responsive intracranial neurostimulator (RNS). The information provided to us by your doctor does not include clinical documentation showing you have a partial or focal seizure disorder.
>
> We have enclosed what we used to make this decision. We used the InterQual Stereotactic Introduction, Subcortical or Cortical Electrodes criterion. This criterion is widely used and developed using evidenced based, peer-reviewed journals, research, and specialists to determine medical necessity. Your Certificate of Coverage states that services and supplies must be medically necessary. We are unable to approve a responsive intracranial neurostimulator (RNS) for you based on the information provided to us.
>
> *Exhibit D, page 1*

6. On March 13, 2023, Petitioner, through her doctor, filed an Internal Appeal with Respondent regarding that decision. (Exhibit B).

7. In part, that appeal included a letter from Petitioner's doctor stating:

> The medical reviewer for [Respondent] denied stating that the service was not medically necessary (denial letter enclosed) because [Petitioner] does not have focal epilepsy. While it is true that my patient does not have focal epilepsy, this service is very much medically necessary and in fact is the only available option for my patient to get her seizures under control.
>
> * * *
>
> Responsive neurostimulator provides a viable and scientifically supporting therapeutic option to control her seizures, mitigate sudden death and it offers a real possibility for her to lead a productive life. This is the most appropriate treatment for my patient at this time and I ask that you approve coverage.

Exhibit B, pages 1, 3

8. The Internal Appeal was sent to a specialty neurologic surgeon for review, who concluded in part:

> **1. Based on the provided guideline/ policy, is the service under review medically necessary? Please explain in detail.**
>
> No. Based on the provided guideline/policy, the service under review is not medically necessary because the policy states that this treatment is indicated for partial or foal seizure disorder and this patient has generalized seizures. Also, it states that the procedure is indicated if the patient has seizures after epilepsy surgery or is not a candidate for epilepsy surgery. There is no indication that this patient has had epilepsy surgery with persistent seizures or is not a candidate for epilepsy surgery.
>
> **2. Based on the latest literature, is the requested service considered experimental or investigational for the treatment of refractory idiopathic generalized epilepsy?**
>
> Yes. Based on the latest literature, the requested service is considered experimental or investigational for the treatment

of refractory idiopathic generalized epilepsy as there is lack of large sample size data to support the efficacy of this treatment. Also, a treatment is experimental if it meets at least one of the criteria listed below:

a) The drug or device cannot be lawfully marketed in the United States without the approval of the Food and Drug Administration (FDA) and that approval has not been granted; NOT MET

b) An institutional review board or other body oversees the administration of the drug, device, treatment, or procedure, or approves or reviews research concerning safety, toxicity or efficacy; NOT MET

c) The patient informed consent documents describe the drug, device, treatment, or procedure as experimental or investigational or in other terms that indicate the service is being evaluated for its safety, toxicity, or efficacy; NOT MET

d) Reliable Evidence shows that the drug, device, treatment, or procedure is:
i) The subject of on-going phase I or phase II clinical trials; NOT MET
ii) The research, experimental study, or investigational arm of on-going phase of clinical trials, NOT MET
iii) Otherwise under study to determine its toxicity, safety, or efficacy as compared with a standard means of treatment or diagnosis; NOT MET

e) Reliable Evidence shows that a majority of experts believe that further studies or clinical trials are needed. MET

3. Does the reviewer agree that the documentation submitted for review does not meet the criteria utilized for evaluation?

Yes, I agree that the documentation submitted for review does not meet the criteria utilized for evaluation.

RATIONALE

The patient is a [redacted]-year-old female who has a history of medically refractory epilepsy. She had a vagal nerve stimulator in place. It has since been turned off due to her inability to tolerate this. Due to lack of long term, large sample size data showing that it is both safe and effective in

> this patient's clinical scenario, the requested treatment is not considered medically necessary and it is experimental/investigational.
>
> *Exhibit G, pages 2-3*

9. On March 15, 2023, Respondent sent Petitioner written notice that her Internal Appeal was denied. (Exhibit I).

10. With respect to the reason for the decision, the notice stated in part:

> **Why did we deny your Internal Appeal?**
>
> We denied your Internal Appeal for the service/item listed above because: Based on InterQual coverage criteria, the service under review is not medically necessary because the policy states that this treatment is indicated for partial or focal seizure disorder and this patient has generalized seizures. Additionally, the coverage criteria states the procedure is indicated if the patient has seizures after epilepsy surgery or is not a candidate for epilepsy surgery.
>
> Available documentation [sic] does not show indication this patient has had epilepsy surgery with persistent seizures or is not a candidate for epilepsy surgery.
>
> *Exhibit I, page 1*

11. On March 17, 2023, the Michigan Office of Administrative Hearings and Rules (MOAHR) received the request for hearing filed by Petitioner in this matter regarding Respondent's decision. (Exhibit A).

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 statute, 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:

> 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**
>
> - Elective therapeutic abortions and related services. Abortions and related services are covered when medically necessary to save the life of the mother or if the pregnancy is a result of rape or incest;

- Experimental/Investigational drugs, procedures or equipment;
- Elective cosmetic surgery; and
- Services for treatment of infertility.

MPM, January 1, 2023 version
Medicaid Health Plan Chapter, pages 1, 4
(Underline added for emphasis)

As allowed by the above policy and its contract with the Department, the MHP has chosen to use its own prior authorization requirements, utilization management, and review criteria. Specifically, as explained by Respondent's witness and demonstrated by its exhibits, Respondent uses InterQual guidelines when reviewing requests.

Moreover, for stereotactic introduction, subcortical or cortical electrodes like what was requested in this case; those guidelines specifically require that a patient be diagnosed with partial or focal seizure disorder.

Accordingly, as Petitioner has not been diagnosed with partial or focal seizure disorder, and instead has a generalized seizure condition, Respondent found that Petitioner failed to meet the applicable criteria and denied her request.

In appealing that decision, Petitioner has the burden of proving by a preponderance of the evidence that Respondent erred in denying her authorization request. Moreover, the undersigned Administrative Law Judge is limited to reviewing Respondent's decision in light of the information that was available at the time the decision was made.

Given the above policy and evidence in this case, Petitioner has failed to satisfy her burden of proof and Respondent's decision must be affirmed. Respondent, as permitted by its contract and the MPM, has developed specific utilization review criteria, consistent with all applicable published Medicaid coverage and limitation policies, regarding responsive intracranial neurostimulators like the one requested by Petitioner, and Petitioner undisputedly does not meet that required criteria given her identified diagnoses.

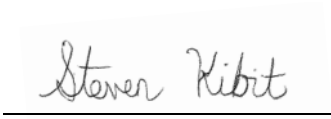
Moreover, while Petitioner seeks an exception to that criteria given her extenuating circumstances, and on the basis of medical necessity, the record further demonstrates that the request is for a non-covered experimental service given the lack of any approval from the Food and Drug Administration (FDA); the provisions of the InterQual guidelines; the findings of the reviewing neurologic surgeon, none of which Petitioner's representative disputed; and Petitioner's representative's concession that the request was for a "nontraditional target," with Petitioner to be part of a study.

DECISION AND ORDER

The Administrative Law Judge, based on the above Findings of Fact and Conclusions of Law, decides that Respondent properly denied Petitioner's prior authorization request.

IT IS, THEREFORE, ORDERED that:

Respondent's decision is **AFFIRMED.**



SK/sj

Steven Kibit
Administrative Law Judge

NOTICE OF APPEAL: Petitioner 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).

PROOF OF SERVICE

I certify that I served a copy of the foregoing document upon all parties and/or attorneys, to their last-known addresses in the manner specified below, this 26th day of April 2023.

S. James

S. James
Michigan Office of Administrative Hearings and Rules

Via Electronic Mail:

Community Health Representative
McLaren Health Plan
Attn: Melissa Sweet
G 3245 Beecher Rd.
Flint, MI 48532
Mhpappeals@mclaren.org

DHHS Department Contact
CCC, 7th Floor
Lansing, MI 48919
MDHHS-MCPD@michigan.gov

Via Fax Mail:

Petitioner
[redacted]
[redacted] MI [redacted]
[redacted]

Authorized Hearing Representative
Dr. Sanjay Patra, MD
25 Michigan St. NE, Suite 6100
Grand Rapids, MI 49503
Fax: 616-267-7551