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GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
MICHIGAN OFFICE OF ADMINISTRATIVE HEARINGS AND RULES

ORLENE HAWKS
DIRECTOR

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██████████ 48093

Date Mailed: May 24, 2021
MOAHR Docket No.: 21-002151
Agency No.: ██████████
Petitioner: ██████████

ADMINISTRATIVE LAW JUDGE: Steven Kibit

DECISION AND ORDER

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

After due notice, a telephone hearing was held on May 18, 2021. Attorney Janet Szpond appeared on Petitioner's behalf. Dr. Stephen Doggett, M.D.; ██████████, Petitioner's sister; and Petitioner; testified as witnesses for Petitioner. Shana Lucas, Appeals and Grievance Coordinator, appeared on behalf of Molina Healthcare of Michigan, the Respondent Medicaid Health Plan (MHP). Dr. Keith Tarter, Chief Medical Director, testified as a witness for Respondent.

During the hearing, an evidence packet previously submitted by Respondent, but also containing documents submitted by Petitioner as part of her request for hearing, was admitted into the record as Exhibit A, pages 1-189.

ISSUE

Did Respondent properly deny Petitioner's prior authorization request for brachytherapy to the lungs?

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 ██████ (████) year-old woman who was diagnosed with adenoid cystic carcinoma (ACC) in the year 2015. (Exhibit A, pages 59-61; Testimony of Petitioner).
2. Petitioner then began receiving treatment for her ACC in both the State of Tennessee and, after she moved, the State of Michigan. (Testimony of Petitioner).

3. By April of 2017, Petitioner's ACC, which was first found in her face, had metastasized to her lungs. (Exhibit A, pages 59-61; Testimony of Petitioner).
4. At that point, Petitioner was advised by her doctors in Michigan that the only treatment options available were clinical trials. (Testimony of Petitioner).
5. Through an ACC support group Facebook site, Petitioner's sister subsequently discovered a radiation oncologist in the State of California, Dr. Stephen Doggett, M.D., who treated ACC in the lungs via brachytherapy. (Testimony of Petitioner's sister).
6. Petitioner's doctor in the State of Michigan then referred Petitioner to Dr. Doggett. (Exhibit A, 28; Testimony of
7. Dr. Doggett is the only practitioner in the United States of America who performs brachytherapy to the lungs for treatment of ACC. (Testimony of Dr. Doggett).
8. He has been performing brachytherapy to the lungs since 1993 and treating ACC for the past 9-10 years. (Testimony of Dr. Doggett).
9. The only other practitioners who now perform the procedure are located in the People's Republic of China. (Testimony of Dr. Doggett).
10. Beginning in December of 2019, Petitioner started receiving brachytherapy to the lungs at a hospital in California, with the procedures performed by Dr. Doggett. (Exhibit A, pages 79-159).
11. Due the amount Petitioner's tumors and constraints on how they can be treated, Petitioner underwent brachytherapy in California in December of 2019 and August of 2020, with further procedures planned. (Exhibit A, pages 76-159; Testimony of Dr. Doggett).
12. The procedures were approved and paid for by Petitioner's private insurance at the time. (Exhibit A, pages 20-24; Testimony of Petitioner).
13. In 2021, Petitioner became a Medicaid beneficiary and enrolled in the Respondent MHP. (Testimony of Petitioner).
14. On April 8, 2021, Respondent received a prior authorization request for brachytherapy to the lungs and related services for Petitioner for treatment of her ACC. (Exhibit A, pages 58-71).
15. As part of that request, Dr. Doggett identified Petitioner's diagnoses as including malignant neoplasm of major salivary gland; secondary malignant neoplasm of right lung; and secondary malignant neoplasm of left lung. (Exhibit A, page 59).

16. Dr. Doggett also specifically identified the following plan of care: “[Petitioner] needs to return here asap for further brachytherapy to both lungs, consideration of tale pleurodesis and potential nerve block.” (Exhibit A, page 60).
17. On April 15, 2021, Respondent sent Petitioner written notice that her request had been denied. (Exhibit A, pages 33-38).
18. With respect to the reason for the denial, the notice stated:

TO MEMBER: The requested Lung Brachytherapy and Services are not a covered benefit. The notes sent in show you have a lesion to your gland in your mouth. Criteria shows that brachytherapy is considered experimental and or investigational. There is not enough proof that brachytherapy has been proven safe and or effective for your condition. Also, your provider is out of state. You can be treated in Michigan at the University of Michigan. Since this is not an emergency and you can be treated in the state of Michigan, this is a non covered [sic] benefit. Therefore, the request is denied. Please speak to your doctor with questions you may have.

TO PROVIDER: The requested Lung Brachytherapy and Services – 77290, 77318, 77470, 77798, 77370, 20555 are denied. Out of state treatment of member’s malignant neoplasm of salivary gland can be treated in Michigan at the University of Michigan. This is not an emergency, and the service is available in Michigan. Additionally, lung brachytherapy for malignant neoplasm of salivary glands appears to be experimental. There are no double blinded studies in a peer reviewed journal supporting this treatment for this condition. Per the Michigan Department of Health and Human Services, Medicaid Provider Manual, 8.3 **NONCOVERED SERVICES**, “Experimental/investigational drugs, biological agents, procedures, devices or equipment” are not covered. Also, out of

state treatment does not meet the Michigan Department of Health and Human Services, Medicaid Provider Manual, 7.3 OUT OF STATE/BEYOND BORDERLAND AND PROVIDERS. Therefore, the request is denied.

Exhibit A, page 33

19. On April 21, 2021, Petitioner requested an Internal Appeal with Respondent regarding the denial of the prior authorization request, with Dr. Doggett identified as her representative. (Exhibit A, pages 71-174).
20. In support of that appeal, Dr. Doggett wrote in part:

I am writing to appeal the health plan's denial of medically necessary treatment for [Petitioner]. [Petitioner] has been under my care since 2019 for her Adenoid Cystic Carcinoma diagnosis, she underwent bilateral CT guided brachytherapy procedures to both lungs at Mission Hospital in mid-December 2019 and August 2020. This course of treatment is prudent and necessary in order to improve, and ultimately maintain her health. In the absence of the medically necessary care, her condition will worsen and irrevocably compromise her health.

Please reconsider your position and allow us to continue treating [Petitioner] in accordance with her medical needs and not based on the economics of the health plan. The treatment and services prescribed are not available in Michigan. The alternate treatment suggested by the health plan is unacceptable to manage her care.

Exhibit A, page 74

21. Dr. Doggett also spoke over the telephone with Respondent's Senior Medical Director, Dr. Keith Tarter, regarding Petitioner's case. (Testimony of Dr. Doggett; Testimony of Dr. Tarter).
22. On April 27, 2021, Respondent sent Dr. Doggett a Physician Reviewer Denial Letter stating that, following a review by a Medical Director for Respondent, the denial was being upheld. (Exhibit A, page 40).

23. With respect to the reason for that decision, the letter stated:

- The request is an experimental treatment, there is no peer reviewed journal supporting lung brachytherapy for malignant neoplasm of salivary gland.
- This is not a covered benefit per MDHHS Provider Manual sections:
 - 7.3 OUT OF STATE/BEYOND BORDERLAND PROVIDERS
MDHHS will only authorize non-emergency services to out of state/beyond borderland if the service is not available within the State of Michigan borderland areas. This procedure is available at the University of Michigan Medicine.
 - 8.3 NONCOVERED SERVICES
Experimental/investigational drugs, biological agents, procedures, devices or equipment are not covered.

Exhibit A, page 40

24. On May 3, 2021, 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, pages 3-56).

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.

*MPM, April 1, 2020 version
Medicaid Health Plan Chapter, page 1
(underline added for emphasis)*

As allowed by the above policy and its contract with the Department, the MHP has developed prior authorization requirements and utilization management and review criteria; and has limited coverage to those consistent with all the Department's applicable published Medicaid coverage and limitation policies.

As part of those policies, the Department's Medicaid Provider Manual (MPM) states in part:

7.3 OUT OF STATE/BEYOND BORDERLAND PROVIDERS [CHANGE MADE 4/1/21]

Reimbursement for services rendered to beneficiaries is normally limited to Medicaid-enrolled providers. *MDHHS reimburses out of state providers who are beyond the borderland area if the service meets one of the following criteria:*

- Emergency services as defined by the federal Emergency Medical Treatment and Active Labor Act (EMTALA) and the federal **(text added 4/1/21)** Balanced Budget Act of 1997 and its regulations; or
- Medicare and/or private insurance has paid a portion of the service and the provider is billing MDHHS for the coinsurance and/or deductible amounts; or
- *The service is prior authorized by MDHHS. MDHHS will only prior authorize non-emergency services to out of state/beyond borderland providers if the service is not available within the state of Michigan and borderland areas.*

Managed Care Plans follow their own Prior Authorization criteria for out of network/out of state services. Providers participating in Medicaid Health Plan and Dental Health Plan networks should refer to the Dental chapter (Healthy Kids Dental section) and the Medicaid Health Plans chapter of this manual for additional prior authorization information.

* * *

8.3 NONCOVERED SERVICES

The items or services listed below are not covered by the Medicaid program:

- Acupuncture
- Autopsy
- Biofeedback

- All services or supplies that are not medically necessary
- *Experimental/investigational drugs, biological agents, procedures, devices or equipment*
- Routine screening or testing, except as specified for EPSDT Program or by Medicaid policy . . .

*MPM, April 1, 2021 version
General Information for Providers Chapter, pages 21, 23
(internal highlighting omitted)
(italics added for emphasis)*

Here, Respondent denied the prior authorization request at issue in this case pursuant to the above policies and coverage limitations, and on the basis that the requested procedure is both experimental and could be provided in the State of Michigan.

Specifically, Respondent's Senior Medical Director testified brachytherapy is done at University of Michigan. However, he also testified that the University of Michigan uses larger pellets; he does not know what body parts the University hospital performs the procedure on; and the specific treatment she seeks is not available in the State of Michigan.

The Senior Medical Director further testified that, when reviewing Petitioner's Internal Appeal, he asked Petitioner's doctor for any peer-reviewed literature that supported the requested treatment as non-experimental or as a standard treatment, and Petitioner's doctor did not provide any. The Senior Medical Director also asked if the treatment was part of National Comprehensive Cancer Network (NCCN) guidelines or part of any double-blinded studies, and Petitioner's doctor said it is not.

Petitioner's doctor did say that he had successfully performed the procedure on patients and that he had case studies. The Senior Medical Director also agreed that the procedure has been successful for Petitioner. He further indicated that he does not know what other options Petitioner has.

The Senior Medical Director could not explain why Medicare might approve the experimental treatment or why her private insurance did approve it, but he further noted that they may have different rules and he only reviewed the case under the applicable Medicaid guidelines.

In response, Petitioner's doctor described the requested procedure and how it is different from anything performed at the University of Michigan. He also testified that the procedure was developed approximately 27 years ago and that he has been performing it since that time. Petitioner's doctor further testified that he is the expert on

the procedure and has published several articles on it in peer-reviewed literature, with another forthcoming, but that he did not submit them as part of the Internal Appeal. He also testified that he assumed Petitioner's attorney had submitted everything as part of the appeal in this case.

Petitioner's doctor also testified that no one else performs the requested procedure in the United States of America or Europe, though some hospitals have started to do so in mainland China. When asked why no one else is doing it, Petitioner's doctor testified that is a vanishing art and that other oncologists go into more financially lucrative areas.

With respect to ACC, Petitioner's testified that he has treated it for 9-10 years. He also testified that it is extremely rare, with only approximately 1,400 new cases per year and only 400 cases per year where the cancer has travelled to the lungs like with Petitioner. In particular, he testified that the condition is too rare for any double-blind studies to be performed or for the NCCN guidelines to mention it at all.

Petitioner's doctor also testified that the procedure is not experimental because Petitioner has had it twice before with success. He also testified that he has never seen a request for it denied before and that Petitioner's only other options are non-effective clinical trials or multiple, consecutive surgeries.

Petitioner's sister testified regarding the history of Petitioner's case and the effect of a delay of treatment on Petitioner. She also testified that she had to perform lots of research of ACC because it was so rare and that she found Petitioner's doctor through a Facebook support group, with Petitioner's doctor at the University of Michigan then referring Petitioner to him. She also testified that it would be so much easier to get the procedure done in Michigan if it was available, but it is not available here and Petitioner has no other options.

Petitioner testified regarding the history of her case, including the fact that her previous private insurance twice approved the requested procedure. She also testified that she only switched insurance after she had to stop working and went on Medicaid. She further testified that she was told by her doctor's office that Medicare would approve the procedure, but she cannot go on Medicare for another 24 months.

With respect to the requested procedure, Petitioner testified that it has killed 55 tumors in her lungs and there is evidence that it works. She also testified that being denied is endangering her life and that she would have it done in Michigan if she could, but that it is not available here. She further testified that the University of Michigan is now referring patients like her to Petitioner's doctor in California.

Petitioner has the burden of proving by a preponderance of the evidence that the MHP 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 policies and evidence in this case, Petitioner has not met her burden of proof and Respondent's decision must therefore be affirmed.

Respondent denied the prior authorization request at issue in this case for two reasons, *i.e.*, that the requested procedure is both experimental and could be provided in the State of Michigan, but the record demonstrates that Respondent clearly erred with that second reason as the requested procedure is not available in Michigan. Specifically, while it is undisputed that brachytherapy is generally available in Michigan, it is likewise undisputed that the brachytherapy to the lungs for the treatment of ACC sought by Petitioner is only available in the country at one location in California.

Nevertheless, even with that error, Respondent's decision must still be affirmed as Petitioner failed to demonstrate that the requested procedure is not experimental.

For example, the fact that the brachytherapy to the lungs for the treatment of ACC sought by Petitioner is only available in one single location in the country, and not at all in Europe, and not performed by any other doctor or any academic institution suggests that it is novel and experimental.

Similarly, the fact that Petitioner's primary oncologist at the University of Michigan was not aware of the treatment and did not initially refer Petitioner for it until after Petitioner's sister discovered it through a Facebook group, and Petitioner expressly requested it, likewise speaks to the lack of recognition or general acceptance of the procedure sought by Petitioner. Petitioner understandably wants to try anything that might work, but that does not mean her request meets Medicaid criteria.

Moreover, while Petitioner's doctor testified that he has published several articles on the procedure in peer-reviewed literature, with another forthcoming, no such articles were included in the Internal Appeal sent to Respondent or as part of any exhibit in this case. Without providing them and allowing Respondent a chance to rebut them, Petitioner's claim of peer-reviewed literature lack much probative value.¹

Petitioner has twice received what she requested in the past, but never under Medicaid guidelines and it is Medicaid coverage limitations, as adopted by Respondent, that apply in this case. And, while the undersigned Administrative Law Judge strongly sympathizes with Petitioner, experimental procedures are not covered under those applicable policies; as described above, that appears to be what Petitioner seeks here; and there is no exception that allows for coverage of experimental treatment just because the patient has found one that appears to work for her.

¹ Petitioner did provide part of a journal article, not by Petitioner's doctor, on brachytherapy as part of the request for hearing, but Respondent's doctor explained why that article did not change Respondent's decision and Petitioner's doctor did not address it all or explain its significance. Accordingly, even putting aside that the entire article was not included, the undersigned Administrative Law Judge does not find that it supports Petitioner's position.

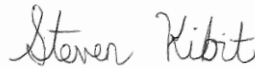
To the extent Petitioner has additional or updated information regarding why the requested procedure is not experimental, then she can always have a new request submitted in the future along with that additional information. With respect to the issue in this case however, Respondent's decision must be affirmed given the available information and applicable policies.

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 authorization request.

IT IS, THEREFORE, ORDERED that:

Respondent's decision is **AFFIRMED**.



SK/sb

Steven Kibit
Administrative Law Judge

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
MDHHS-MCPD@michigan.gov

Petitioner

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