



GRETCHEN WHITMER
GOVERNOR

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

ORLENE HAWKS
DIRECTOR

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████████████████████, MI ██████████

Date Mailed: July 1, 2021
MOAHR Docket No.: 21-002235
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 June 9, 2021. Dr. ██████████, M.D., appeared and testified on Petitioner's behalf, with Petitioner and ██████████, Authorization Specialist, also present. 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.

Prior to the hearing, Respondent submitted an evidence packet as a proposed exhibit. However, Petitioner did not receive a copy and the copy sent to the Michigan Office of Administrative Hearings and Rules (MOAHR) was incomplete. Accordingly, while the packet was discussed briefly during the hearing, it was not admitted at that time and the record was left open so that Petitioner's representative could review the proposed exhibit and object to its admission if he wished.

Following the hearing, Petitioner's representative timely submitted a letter. He did not object to the admission of Respondent's proposed exhibit in that letter and, consequently, Respondent's evidence packet was admitted as Exhibit A, pages 1-97.

ISSUE

Did Respondent properly deny Petitioner's prior authorization request for proton beam radiation therapy?

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 [REDACTED] ([REDACTED]) year-old Medicaid who was diagnosed with esophageal cancer in 2015. (Exhibit A, page 42).
2. He then underwent radiation in 2015 and 2016, and an esophagectomy in 2016. (Exhibit A, page 42).
3. In March of 2021, Petitioner was evaluated by a Dr. [REDACTED] and diagnosed with left upper lobe lung cancer and malignant neoplasm of cardia. (Exhibit A, pages 39, 42-43).
4. On April 1, 2021, Respondent received a prior authorization request from Dr. [REDACTED] for proton beam radiation therapy services for Petitioner for treatment of his lung cancer. (Exhibit A, pages 38-55).
5. As part of that request, Dr. [REDACTED] included a Treatment Planning Note stating in part that:

Proton Therapy was utilized because the more conformal dose distribution would optimize target coverage and dose heterogeneity while improving sparing of the critical normal tissues as compared to photon techniques.

Exhibit A, page 40

6. The prior authorization also included a report following an evaluation of Petitioner in March of 2021 in which the following plan of treatment was identified:

PLAN: I discussed with the patient that if we are to perform radiation, it would be using proton therapy due to his prior radiation therapy in this area. He is at increased risk of side effects due to the prior radiation of the mediastinal structures, bones, spinal cord, and major blood vessels and nerves in this area. There can be chronic pain due to rib, nerve, or airway damage. There can be long term pleurisy. Cough and shortness of breath may occur due to radiation of the lungs and airways. Because his stomach is now in the central mediastinum, radiation to the stomach in this

area can cause ulceration which could bleed, possibly requiring endoscopic cauterization or maybe even open surgical repair.

* * *

Proton therapy is medically necessary in his case due to prior mediastinal radiation therapy to high doses. The organs at risk in this area include the lung, the gastric pull up, the airways, the heart and spinal cord. By the use of proton therapy, we can meaningfully decrease the risks of repeated irradiation. Nevertheless, even with protons, there can still be severe even potentially life-threatening complications when performing re-irradiation to any major organ.

Exhibit A, page 44

7. On April 8, 2021, Respondent sent Petitioner written notice that his request had been denied. (Exhibit A, pages 86-90).
8. With respect to the reason for the denial, the notice stated:

Based on eviCore Radiation Oncology Guidelines For Treatment by Site: Non-Small Cell Lung Cancer, we cannot approve the request. Your records show that you have cancer. The reason this request cannot be approved is because there is no current research showing that your type of cancer responds better to the requested type of treatment than the type of treatment we can approve. This type of treatment is called IMRT (Intensity-Modulated Radiation Therapy). This type of treatment changes the shape and strength of the beams during treatment. IMRT would be approved if requested. We have told your doctor about this. Please talk to your doctor if you have questions.

Exhibit A, page 86

9. On April 19, 2021, Petitioner requested an Internal Appeal with Respondent regarding the denial of the prior authorization request, with Dr. [REDACTED] as his authorized representative. (Exhibit A, pages 56-84).

10. As part of the Internal Appeal, a letter from Dr. [REDACTED] was included. (Exhibit A, pages 57-58)

11. In part, that letter stated:

The patient's large area of lymph node involvement necessitates treatment with large thoracic fields which will directly overlap with large volumes of his lung, heart, esophagus, and gastric-pull up. There is a risk of ulceration in the esophageal and gastric tissues unless a very compact dose of radiation can be delivered, which proton therapy can do more safely than X-ray therapy.

In fact, one of the many clinical indications for proton therapy that is cited by ASTRO (The American Society for Radiation Oncology) in its model policy document is for re-irradiation:

"4. The same or an immediately adjacent area had been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby tissue."

Exhibit A, page 57

12. Dr. [REDACTED]'s letter also identified where that policy document from ASTRO could be located. (Exhibit A, page 57)

13. The letter further identified and provided citations for six "[s]cientific references justifying proton therapy for thoracic re-irradiation". (Exhibit A, page 58).

14. On April 19, 2021, Respondent sent Petitioner and his doctor a letter stating that, following review of the Internal Appeal, the denial was being upheld. (Exhibit A, pages 92-94).

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

Upon review, the service is not authorized because it is not Medically Necessary. Based on eviCore Radiation Oncology Guidelines For Special Techniques: Proton Beam Therapy, we cannot approve this request. Your records show that you have cancer. The reason this request cannot be approved is because there is no current research showing that your type

of cancer responds better to the requested type of treatment than the type of treatment we can approve. This type of treatment is called IMRT (Intensity-Modulated Radiation Therapy). This type of treatment changes the shape and strength of the beams during treatment. IMRT would be approved if requested. We have told your doctor about this. Please talk to your doctor if you have questions.

Your appeal was thoroughly considered by an appeal nurse reviewer and an eviCore Medical Director, who is a Medical Director and is board certified in Radiation Oncology.

Exhibit A, page 92

16. On May 5, 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 3-36).

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, 2021 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. In part, that policy provides:

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

*MPM, April 1, 2021 version
General Information for Providers Chapter, page 23*

(underline added for emphasis)

Here, Respondent denied the prior authorization request at issue in this case pursuant to the above policies and on the basis that the requested procedure is experimental.

Specifically, Respondent's Senior Medical Director testified that, while he is not familiar with Petitioner's condition, Respondent hires eviCore radiation oncologists to review complex cases like Petitioner's and they determined that the request should be denied on the basis that IMRT is the standard treatment. He also testified that, as Petitioner's requested treatment is non-standard, it is therefore experimental. He further testified that, while proton beam therapy is not experimental in general, it is for Petitioner's condition.

In response, Petitioner's representative/treating physician testified that, while IMRT is standard treatment for brand-new cancer cases, it is not the standard treatment in cases like Petitioner's, where he has a history of cancer and previous radiation treatment. The treating physician also testified that the previous radiation makes radiation for Petitioner at this time unsafe, unless done with proton beams, and that proton beam therapy has long been approved by the FDA and covered by Michigan Medicaid. He further testified that Petitioner's situation is not a new problem, and the proton beam radiation therapy is not a new use for that problem, and he noted that his testimony is supported by the scientific literature he provided as part of the Internal Appeal.

Petitioner has the burden of proving by a preponderance of the evidence that the MHP erred in denying his 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 met his burden of proof and Respondent's decision must therefore be reversed.

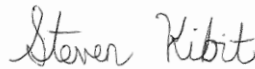
Petitioner's treating physician credibly and fully explained during his testimony why the requested proton beam radiation therapy is both necessary in Petitioner's specific case and non-experimental, and that testimony is essentially uncontradicted. While Respondent's Medical Director testified in general as to the basis for Respondent's decision, he also conceded that he is unfamiliar with Petitioner's particular case, and he could not address the treating physician's testimony, or the literature cited in support of the request. Moreover, while Respondent hired radiation oncologists to review the request, those oncologists did not testify during the hearing and nowhere in the record do they address Petitioner's doctor's specific and clear arguments or the literature he cited. Accordingly, the undersigned Administrative Law Judge gives their conclusory denials little weight and, given the clear, credible and uncontradicted testimony of Petitioner's treating physician demonstrating the necessity and nonexperimental nature of the requested treatment, he finds that Respondent erred.

DECISION AND ORDER

The Administrative Law Judge, based on the above Findings of Fact and Conclusions of Law, decides that Respondent erred in denying Petitioner's authorization request for proton beam radiation therapy.

IT IS, THEREFORE, ORDERED that:

Respondent's decision is **REVERSED**, and it must initiate a reassessment of Petitioner's request for services.



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

Authorized Hearing Rep.

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