STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
OFFICE OF INSPECTOR GENERAL

Jeffrey H. Coben, M.D.
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Sheila Lee
Interim Inspector General

December 28, 2022

[redacted]

RE: [redacted] v. WV DHHR
ACTION NO.: 22-BOR-2486

Dear [redacted]:

Enclosed is a copy of the decision resulting from the hearing held in the above-referenced matter.

In arriving at a decision, the State Hearing Officer is governed by the Public Welfare Laws of West Virginia and the rules and regulations established by the Department of Health and Human Resources. These same laws and regulations are used in all cases to assure that all persons are treated alike.

You will find attached an explanation of possible actions you may take if you disagree with the decision reached in this matter.

Sincerely,

Lori Woodward, J.D.
Certified State Hearing Officer
Member, State Board of Review

Encl: Recourse to Hearing Decision
Form IG-BR-29

cc: Bureau for Medical Services
[redacted]

WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BOARD OF REVIEW

[redacted],

Appellant,

v. **ACTION NO: 22-BOR-2486**

WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES,

Respondent.

DECISION OF STATE HEARING OFFICER

INTRODUCTION

This is the decision of the State Hearing Officer resulting from a fair hearing for [redacted]. This hearing was held in accordance with the provisions found in Chapter 700 of the West Virginia Department of Health and Human Resources' Common Chapters Manual. This fair hearing was convened on December 20, 2022, on an appeal filed November 3, 2022.

The matter before the Hearing Officer arises from the Respondent's September 19, 2022 and October 31, 2022 denials for pre-authorization of Durable Medical Equipment (DME).

At the hearing, the Respondent appeared by Anita Ferguson with Bureau for Medical Services. Appearing as witnesses for the Respondent were Dr. Sanjoydeb Mukherjee, Amber Nary, Randy Stoker, Adrienne Matthews, all with UniCare, and Dr. Gregg Golden with Advanced Medical Review. The Appellant was represented by [redacted] with Novocure. Appearing as a witness for the Appellant was [redacted] with Novocure. All witnesses were placed under oath and the following documents were admitted into evidence:

Department's Exhibits:

- D-1 UniCare Health Plan of West Virginia Medicaid Summary
- D-2 Prior Authorization Request dated June 22, 2022
- D-3 Prior Authorization Denial Letter dated June 24, 2022
- D-4 Member Appeal, Level 1 Appeal, Out of Network Exception dated August 17, 2022
- D-5 UniCare Appeal Acknowledgement Letter dated August 19, 2022
- D-6 UniCare Peer Reviewer Final Report dated September 6, 2022
- D-7 UniCare Notice of Appeal Resolution dated September 8, 2022
- D-8 Request for State Fair Hearing dated November 3, 2022
- D-9 Optune/Optune Lua Prescription Form, dated June 20, 2022
- D-10 Novocure Invoice, dated June 22, 2022

D-11 [redacted] Medicine, [redacted] Medical Center, physician notes April 29 and May 2, 2022; Genesis Care physician notes May 18, 2022
D-12 Anthem Blue Cross Clinical UM Guideline (CG-DME44), Electric Tumor Treatment Field (TTF)
D-13 UniCare Health Plan of West Virginia Medicaid Summary
D-14 Prior Authorization Request dated September 14, 2022
D-15 Prior Authorization Denial Letter dated September 19, 2022
D-16 Member Appeal, Level 1 Appeal, Out of Network Exception dated October 31, 2022
D-17 UniCare Acknowledgement of Expedited Appeal Request dated November 1, 2022
D-18 UniCare Peer Reviewer Final Report dated September 16, September 19, and November 1, 2022
D-19 UniCare Notice of Appeal Resolution dated November 2, 2022
D-20 Request for State Fair Hearing dated November 3, 2022
D-21 Optune/Optune Lua Prescription Form, dated June 20, 2022
D-22 Novocure Invoice, dated June 22, 2022
D-23 Genesis Care physician notes August 1, 2022
D-24 Anthem Blue Cross Clinical UM Guideline (CG-DME44), Electric Tumor Treatment Field (TTF)

*NOTE: Department Exhibits were originally labeled Exhibits A - L in two separate evidence packets. They have been combined and relabeled D-1 - 24

Appellant's Exhibits:

A-1 West Virginia DHHR Pre-Hearing and/or Fair Hearing Request Form (DFA-FH-1); Request for State Fair Hearing Letter dated October 31, 2022 for denial of DME for date of service June 2 – September 19, 2022
A-2 Prior Authorization Denial Letter dated September 19, 2022 for date of service September 14 – December 12, 2022
A-3 [redacted] Medicine, [redacted] Medical Center MRI, physician notes October 18, 2022
A-4 Member Appeal, Level 1 Appeal, Out of Network Exception dated August 17, 2022; Prior Authorization Denial Letter dated June 24, 2022; Novocure Invoice, dated June 22, 2022; GenesisCare physician notes dated August 1, 2022; GenesisCare May 18, 2022 outpatient consultation report; [redacted] Cancer Institute Return Patient Progress Notes dated July 5, 2022; [redacted] Medicine, [redacted] Medical Center CT Report dated April 29, 2022; [redacted] Medicine [redacted] Medical Center MRI report dated April 29, 2022; [redacted] Medical Center Department of Pathology and Laboratory Medicine report
A-5 NCCN (National Comprehensive Cancer Network) Clinical Practice Guidelines in Oncology Version 1.2018
A-6 JAMA Oncology articles; Journal of Neuro-Oncology Clinical Study
A-7 April 8, 2011 and October 15, 2015 letters from the Centers for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)
A-8 Optune Instructions for Use (NOTE: most of exhibit is too light to read)
A-9 The Society for NeuroOncology (SNO) Interim Analysis of the EF-14 Trial, November 15, 2014

A-10 July 26, 2013 letter from the Centers for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA)
A-11 Novocure Optune Clinical Dossier, Tumor Treating Fields Therapy, Treatment for Glioblastoma Multiforme
A-12 Clinical Practice Experience with Novo TTF-100A System for Glioblastoma: The Patient Registry Dataset (PRiDe); Neuro-Oncology article; British Journal of Cancer (BJC) article; SciVerse Science Direct article; Gutin & Wong article; PNAS article; Cancer Research article; BMC research article; BMC Medical Physics research article; Expert Opinion article
A-13 Copy of July 2, 2013 Redacted letter from Chicago CMS Regional Office
**NOTE: Appellant Exhibits were originally separated by bullet points. They have been relabeled A-1 – 13. Bullet point labeled "CMS Fee Schedule Update" was not found in packet

After a review of the record, including testimony, exhibits, and stipulations admitted into evidence at the hearing, and after assessing the credibility of all witnesses and weighing the evidence in consideration of the same, the Hearing Officer sets forth the following Findings of Fact.

FINDINGS OF FACT

1) The Appellant was diagnosed with oligodendroglioma, WHO (World Health Organization) Grade III, in May 2022. (Exhibit D-4)

2) As part of her treatment plan, the Appellant was prescribed an Electric Tumor Treatment Field (TTF) device, Optune. (Exhibit D-9)

3) On June 22, 2022, the Appellant requested pre-authorization from her West Virginia Medicaid provider, UniCare, for a three-month rental of Optune from June 6, 2022 to September 19, 2022. (Exhibit D-2)

4) On June 24, 2022, UniCare denied the Appellant's June 2022 request stating that based upon the Clinical UM Guideline for TTF, it was not medically necessary as she was diagnosed with oligodendroglioma. (Exhibit D-3)

5) On August 17, 2022, the Appellant filed a Level 1 Appeal, Out of Network Exception, with UniCare. (Exhibit D-4)

6) On August 17, 2022, UniCare received the appeal, and a peer-to-peer review was initiated. (Exhibits D-5 and D-6)

7) On September 8, 2022, UniCare sent notification to the Appellant that the June 24, 2022 denial was upheld because she did not have the type of tumor (glioblastoma) for which the treatment is used. (Exhibit D-7)

8) On September 14, 2022, the Appellant requested pre-authorization for a three-month Optune rental from September 14, 2022 to December 10, 2022. (Exhibit D-14)

9) On September 19, 2022, UniCare denied the September 2022 pre-authorization request stating that it was determined that the treatment was not medically necessary as defined by the Clinical UM Guideline as she had a grade III brain tumor (oligodendroglioma), and the device is only used for glioblastoma. (Exhibit D-15).

10) On October 31, 2022, the Appellant filed an Urgent Level 1 Appeal, Out of Network Exception. (Exhibit D-16)

11) On November 1, 2022, UniCare received the appeal, and an expedited peer-to-peer review was initiated. (Exhibits D-17 and D-18)

12) On November 2, 2022, UniCare sent notification to the Appellant that the September 19, 2022 pre-authorization denial was upheld because it was determined that it was not medically necessary for her type of brain cancer. (Exhibit D-19)

13) Medical treatment with Optune has been approved for treatment of adult patients with histologically confirmed glioblastoma multiforme (GBM) or WHO grade IV astrocytoma. (Exhibits A-7, A-8, A-11, A-13, and D-12)

APPLICABLE POLICY

Bureau of Medical Services (BMS) policy manual, Chapter 506, Appendix 506A, Covered DME Supplies, E0766, Electrical Stimulation Device Used for Cancer Treatment, Includes All Accessories, Any Type, Prior Authorization, 10 month cap rental.

Anthem BlueCross Clinical UM Guideline, CG-DME 44, Electric Tumor Treatment Field (TTF), explains that the use of FDA approved devices to generate TTF to treat histologically confirmed supratentorial glioblastoma (known also as glioblastoma multiforme (GBM) or WHO grade IV astrocytoma) is considered medically necessary as adjunctive treatment when all listed criteria are met. The use of devices to generate TTF is considered not medically necessary when the criteria listed under medically necessary section are not met and for all other malignant tumors.

DISCUSSION

In May 2022, the Appellant was diagnosed with oligodendroglioma, WHO grade III. As part of her treatment, the Appellant was prescribed the use of Optune, a type of electrical stimulation device. On June 20, 2022, the Appellant requested pre-authorization for Optune use for a three month period from June 22 through September 19, 2022. The Appellant's West Virginia Medicaid provider, UniCare, denied the pre-authorization request on June 24, 2022, finding that the use of Optune was considered not medically necessary for the Appellant's diagnosis of oligodendroglioma (WHO grade III). The Appellant made a member appeal to UniCare on August

17, 2022. On September 8, 2022, UniCare upheld the denial stating that the Appellant did not have the type of brain tumor for which Optune treatment is used.

On September 14, 2022, the Appellant requested pre-authorization approval for a three month rental of Optune from September 14 – December 10, 2022. On September 19, 2022, UniCare denied pre-authorization finding that the use of Optune for the Appellant's type of brain tumor is not considered to be medically necessary, and that the device is only used for a different type of brain tumor, GBM or grade 4 astrocytoma. The Appellant appealed the denial to UniCare, who upheld its denial on November 2, 2022. The Appellant requested a state fair hearing on UniCare's denial.

Optune was approved by the FDA for treatment in adult patients with a GBM or WHO grade IV astrocytoma sometime in 2011. Optune is an electrical stimulation device used for cancer treatment, HCPCS Code E0766. Under BMS policy, pre-authorization for this equipment rental is required and is limited to a total of ten months. In determining whether to pre-authorize the treatment of the Appellant's oligodendroglioma with Optune, UniCare relied upon Anthem BlueCross Clinical UM Guideline Number CG-DME-44 for Electric Tumor Treatment Field (TTF). Optune is found to be a medically necessary treatment for those with a diagnosis of GBM or WHO grade IV astrocytoma as long as other conditions are met. Optune treatment for the Appellant's diagnosis is not considered medically necessary.

Additionally, the Appellant's evidence showed that Optune treatment is only used for those with a diagnosis of GBM or WHO grade IV astrocytoma. In Novocure's own Optune Clinical Dossier, titled "Tumor Treating Fields Therapy, Treatment for Glioblastoma Multiforme" (Exhibit A-11), it discusses under "Description and Use of Optune, Indications for Use," that Optune is intended as a treatment for adult patients (22 years of age or older) with histologically confirmed GBM. Also, in the Appellant's submitted exhibit, "Optune Instructions for Use" (Exhibit A-8) under "Optune Indications for Use", it explains that Optune is intended as treatment for adult patients with histologically confirmed GBM.

The Board of Review lacks the authority to change or make exceptions to policy. Instead, the Hearing Officer must decide whether the Respondent followed policy in rendering its decision. There was no evidence or testimony presented to show that there are any policy exceptions which would allow the rental of Optune for the treatment of Appellant's diagnosis of oligodendroglioma. The evidence presented showed by a preponderance of evidence that Optune treatment has only been approved for the use in adult patients with GBM or WHO grade IV astrocytoma and, therefore, the Respondent's decision to deny pre-authorization for its use is affirmed.

CONCLUSIONS OF LAW

1) Optune, an Electrical Stimulation Device used for adult patients with a diagnosis of GBM or WHO grade IV astrocytoma, must be pre-authorized.

2) Optune treatment for the Appellant's diagnosis of oligodendroglioma is not considered to be medically necessary.

3) The Respondent correctly denied pre-authorization for the use of Optune for the Appellant's diagnosis of oligodendroglioma.

DECISION

It is the decision of the State Hearing Officer to **uphold** the Respondent's decision to deny the Appellant's request for pre-authorization for the rental of Optune.

ENTERED this 28th day of December 2022.

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Lori Woodward, Certified State Hearing Officer