



**STATE OF WEST VIRGINIA  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES  
Office of the Inspector General**

**Sherri A. Young, DO, MBA, FAAFP  
Interim Cabinet Secretary**

**Christopher G. Nelson  
Interim Inspector General**

December 19, 2023

[REDACTED]

RE: [REDACTED] v. WV DHHR  
ACTION NO.: 23-BOR-3407

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

**WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES  
BOARD OF REVIEW**

██████████,

**Appellant,**

v.

**ACTION NO: 23-BOR-3407**

**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 ██████████. 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 13, 2023, on an appeal filed November 1, 2023.

The matter before the Hearing Officer arises from the Respondent's June 14, 2023 denial 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, Lisa Witten, Morgan Cox, RN, all with UniCare. The Appellant was represented by ██████████. Appearing as a witness for the Appellant was ██████████. All witnesses were placed under oath and the following documents were admitted into evidence:

**Department's Exhibits:**

- D-1 May 1, 2023 Request for Continued Authorization E0766 Network Exception and Single Case Agreement – Urgent; March 22, 2023 Optune/Optune Lua Prescription Form; March 3, 2023 MRI Brain results; March 14, 2023 Neuro surgery physician notes
- D-2 Prior Authorization Denial Letter dated May 3, 2023
- D-3 Prior Authorization Appeal for Code E0766 Denial dated June 12, 2023; Letter from ██████████ dated June 11, 2023; Prior Authorization Denial Letter dated May 3, 2023, page 1; UniCare Member Appeal Representative Form dated April 6, 2023; March 22, 2023 Optune/Optune Lua Prescription Form; October 6, 2022 ██████████ Outpatient Consultation Report; October 7, 2022 Oncology physician notes; Learn About Optune pamphlet

- D-4 UniCare Appeal Acknowledgement Letter dated June 13, 2023
- D-5 UniCare Appeal report dated June 14, 2023
- D-6 Amerigroup Clinical UM Guideline (CG-DME44), Electric Tumor Treatment Field (TTF) , published November 17, 2022
- D-7 UniCare Health Plan of West Virginia, Inc., Member Handbook, excerpt
- D-8 Bureau of Medical Services (BMS) policy manual, Chapter 506, Appendix 506A: Covered DME Supplies (excerpt)

**Appellant's Exhibits:**

None

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 is the recipient of WV Medicaid.
- 2) One of the Managed Care Organizations (MCOs) which the Respondent maintains a contractual relationship is with UniCare Health Plan (UniCare) to provide services related to the administration of Medicaid benefits, including prior authorizations and determinations of medical necessity for requests from Medicaid recipients.
- 3) The Appellant was diagnosed with glioblastoma (GBM) in 2019.
- 4) The Appellant was treated with an Electric Tumor Treatment Field (TTF) device, Optune (DME Code E0766), on November 19, 2019, with the last use in December 2022. (Exhibit D-1)
- 5) There is a concern that the Appellant has a recurrence of the GBM, however, it has not been confirmed. (Exhibit D-1)
- 6) On May 1, 2023, the Appellant requested pre-authorization from her West Virginia Medicaid provider, UniCare, for a three-month rental of Optune (May 2 – August 1, 2023). (Exhibit D-1)
- 7) On May 3, 2023, UniCare denied the Appellant's May 1, 2023 request stating that the Appellant had exceeded her 10 month rental coverage limit provided by her plan and has not shown that there has been a recurrence of her GBM. (Exhibit D-2)
- 8) The May 3, 2023 letter also indicated that the denial was based upon unclear records that there has been a recurrence of the GBM, therefore, there was no evidence that it was medically necessary at that time. (Exhibits D-2 and D-5)

- 9) On June 12, 2023, the Appellant filed a prior authorization appeal for the DME Code E0766 denial. (Exhibit D-3)
- 10) On June 13, 2023, UniCare received the appeal, and a review was initiated. (Exhibits D-4)
- 11) On June 14, 2023, UniCare sent notification to the Appellant that the May 3, 2023 denial was upheld. (Exhibit D-5)

### **APPLICABLE POLICY**

**West Virginia Bureau for Medical Services (BMS) Provider Manual, Chapter 100, §100.9, *Prior Authorization Of Services***, states in part: “The BMS, in its sole discretion, determines what information is necessary to approve a prior authorization request. Prior authorization does not, however, guarantee payment. All other requirements must be met for payment. Medical review organizations under contract to BMS are the final clinical authority.”

**West Virginia Bureau for Medical Services (BMS) Provider Manual, Chapter 527, §527.4.1, *General Requirements for Covered Services***: General requirements include, but are not limited to:

- Services must be medically necessary and associated documentation must be maintained;
- The BMS Medicaid Provider Manual is the source of authority for defining minimum state plan covered services;
- Providers must obtain all necessary service authorizations as specified by the MCO; and
- Members must follow MCO requirements with respect to choice of providers and coordination of benefits.

**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.

Amerigroup 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 November 2019, the Appellant was diagnosed with glioblastoma (GBM). As part of her treatment, the Appellant began Optune, a type of electrical stimulation device, on November 19, 2019, which continued until December 2022. On May 1, 2023, the Appellant requested pre-authorization for Optune use for a three month period from May 2 through August 1, 2023. The

Appellant's West Virginia Medicaid provider, UniCare, denied the pre-authorization request on May 3, 2023, finding that the Appellant had exceeded the 10-month rental limit for the electrical stimulation device, Optune (DME E0766). Additionally, the May 3, 2023 denial letter noted that there was no indication that the Appellant had a recurrence of her GBM and, therefore, was not deemed to be medically necessary at that time. The Appellant made a member appeal to UniCare on June 12, 2023. On June 14, 2023, UniCare upheld the denial. The Appellant requested a state fair hearing on UniCare's denial.

Optune was approved by the FDA for treatment in adult patients with 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.

The Appellant's witness, [REDACTED] testified that the Appellant is considered to be newly diagnosed with GBM, even though she had been originally diagnosed and treated with Optune in 2019. [REDACTED] explained that although there was a concern that there was a recurrence of the GBM, there has not been a definitive finding to date. [REDACTED] maintained that under Medicare policy, Optune is a medically necessary treatment for the Appellant's GBM. The Respondent's witness, Dr. Sanjoydeb Mukherjee, maintained that policy limits the payment for the rental of the device to a lifetime total of 10 months, which the Appellant had previously reached. Although Nurse [REDACTED] testified that [REDACTED] has not received any payments for Optune, the Appellant's representative, [REDACTED] testified that their records do not show any payments for 2023. Dr. Mukherjee testified that UniCare had made a total of 10 months payments for the Optune device on behalf of the Appellant, previous to the May 2023 request. The evidence also showed that the Appellant's last use of Optune was in 2022.

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. Policy clearly states that covered DME supplies, E0766, *Electrical Stimulation, Device Used for Cancer Treatment, Includes all Accessories, Any Type*, requires prior authorization and has a 10-month rental cap. Because the Appellant has reached her 10-month rental cap for DME E0766, the Respondent's decision to deny pre-authorization for Optune 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 and has a 10-month rental.
- 2) The Appellant was diagnosed with GBM in 2019 with treatments beginning on November 19, 2019 with Optune, ending in December 2022.
- 3) The Appellant has not been found to have a recurrence of her GBM.
- 4) The Appellant has met her 10-month rental limit for Optune.
- 5) The Respondent correctly denied pre-authorization for the use of Optune.

### **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 19<sup>th</sup> day of December 2023.**

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Lori Woodward, Certified State Hearing Officer