STATE OF FLORIDA
DEPARTMENT OF CHILDREN AND FAMILIES
OFFICE OF APPEAL HEARINGS

[redacted]

APPEAL NO. 14F-10259

PETITIONER,

Vs.

AGENCY FOR HEALTH
CARE ADMINISTRATION
CIRCUIT: 08 Alachua
UNIT: AHCA

RESPONDENT.
_____/

FINAL ORDER

Pursuant to notice, the undersigned convened a telephonic administrative hearing in the above-referenced matter on January 23, 2015 at 2:11 p.m.

APPEARANCES

For the Petitioner: [redacted] case manager with Novocure

For the Respondent: Jackie Allison, program analyst
Agency for Health Care Administration

STATEMENT OF ISSUE

The petitioner appeals with respondent's denial of his request for Medicaid coverage of a Novo TTF-100A device.

PRELIMINARY STATEMENT

The Agency for Health Care Administration (the Agency or AHCA or respondent) administers the Florida Medicaid Program. The Agency contracts with numerous health plans to provide medical services to its program participants. Sunshine State Health Plan (Sunshine) is the contracted provider in the instant case.

By notice dated August 4, 2014, Sunshine informed the petitioner that his request for coverage of a Novo TTF-100A device was denied. The notice reads in relevant part: "The request for Novo TTF-100A is denied as investigational/experimental. Review of literature shows there is 'insufficient' evidence to assess the safety and/or impact on health outcomes or patient management of the Novo TTF-100A System for the treatment of brain tumors."

The petitioner requested reconsideration. By notice dated August 15, 2014, Sunshine informed the petitioner that its original decision was upheld. The notice reads in relevant part:

> The entire case was reviewed by Sunshine Health's Medical Director who is a Board certified MD. ... The treatment is considered experimental and investigational; AHCA contract does not cover experimental and investigational treatments. In conclusion, based on the clinical information provided, standards of practice, current medical literature the coverage of Novo TTF-100A System for the treatment of brain tumors is not considered medically necessary.

On November 12, 2014, the petitioner timely requested a hearing to challenge the denial decision.

There were no additional witnesses for the petitioner. Petitioner's Composite Exhibit 1 was admitted into evidence.

Present as witnesses from the respondent were Paula Dailey, hearing coordinator with Sunshine and Dr. Jeffrey Martorana, chief medical officer with Sunshine.

FINDINGS OF FACT

1. The petitioner (age 49) is a Florida Medicaid recipient. Sunshine is the petitioner's contracted Medicaid services provider.

2. The petitioner describes his medical condition in a Summary of Matters:

> I am a young 49 year old man who has been diagnosed with recurrent glioblastoma multiforme [brain cancer]. I was formerly employed as a construction equipment operator, and worked in the construction business for 20 years up until my diagnosis. ...I have always been a man on the go and have always lived life to the fullest. ...Since my diagnosis in 2013, I have endured multiple chemotherapies such as Temodar, as well as surgical and radiological interventions. I have tried everything to control this awful cancer which has caused me stomach problems, headaches and fatigue. Despite all these treatments, my cancer continued to progress...I had exhausted all 'standard of care' treatments and on September 2, 2014, I began utilizing Novo TTF Therapy.

3. Novo TTF-100A is a "portable battery operated medical device that connects to the scalp [and] creates an electronic field around the tumor to interrupt growth and reproduction of cancer cells." The petitioner's treating physician describes Novo TTF-100A therapy as his best treatment option in a letter to Sunshine dated August 18, 2014. The letter reads in relevant part:

> [the petitioner] has presented with inoperable recurrent glioblastoma and clearly exhausted FDA approved options available to him in this clinical scenario. His is not a candidate for surgical resection. External beam radiation therapy is not a viable option since he has failed this treatment modality. Given the lack of FDA approved options available in this treatment scenario, it is my professional opinion that the best treatment option for his disease at this time is TTF therapy with the Novo TTF-100A system.

4. The Novo TTF-100A was approved by the Food and Drug Administration (FDA) in 2011. A phase three clinical trial was conducted with 237 patients with recurrent glioblastoma that had exhausted surgical and radiation treatment options. The Novo TTF-100A results were compared to the results the patients received after standard care (chemo, radiation, surgery). The results showed that the Novo TTF-100A was no more effective in the treatment of cancer than standard care. However the results show that the Novo TTF-100A causes fewer "adverse events" to other major organs than chemotherapy. The trial concluded that the Novo TTF-100A is comparable to chemotherapy.

5. All Medicaid goods and services must be medically necessary as determined through a prior service authorization process. Sunshine completed the prior service authorization review in the instant case. Sunshine explains its review process in a Summary of Matters which reads in relevant part:

> Based upon review of the member's history since his effective date with the Plan, it is determined that our member is a 48y/o male who was diagnosed with a Brain Tumor on May 2013; after having a seizure. (Glioblastoma). His Oncologist is [redacted]. In May 2013, he began radiation therapy and subsequently on June 11, 2013, commenced with Temodar treatment w/radiation. The member continued with the treatment until MRI of June 2014, indicated the progression of the disease. At that time, Mr. [redacted] underwent a craniotomy w/resection of his recurring tumor on June 30, 2014.
>
> On July 30, 2014, Dr. [redacted] outlined a prescription and order form of NovoTFF-100A System for Mr. [redacted] indicating a start date of this system to be on August 5, 2014. The proposed time of rental is outlined at a six (6) months / $21,000.00 Novocare Invoice.
>
> On August 4, 2014, a denial letter was issued from SH Medical Department in response to the provider's request dated July 30, 2014, for NovoTFF-100A System. The denial reason outlined that the request was determined to be investigational/experimental. Based upon this denial, the provider submitted an appeal to the Appeals & Grievance Department.

On August 7, 2014, a first level review was completed by SH. It was determined that the denial was upheld per SH clinical policy for medical necessity (CP.MP.68). It additional outlined within this denial letter that the AHCA does not cover experimental/investigational treatments.

On September 12, 2014, a second level review was received by the Appeals and Grievance Department. At this time, this case was referred to an outside medical consultant for an independent review. The rationale concluded based upon the completion of this review is as follows: " The requested E0766-Novo TTF 100A Plus Transducers Arrays is considered experimental/investigational. Novo TTF-100 carries a category 3 level recommendation from the NCCN (significant disagreement among panel members that the proposed therapy is of clinical benefit). A category 3 level recommendation from the NCCN is considered non- endorsement of a particular therapy. As the NCCN, the accepted standard guidelines for cancer care in the United States does not endorse this therapy, it is experimental/investigational per policy. The requested E0766-Novo TTF 100A Plus Transducers Arrays is not medically necessary as there are other treatment options listed by the NCCN with broader support such as CPT-11, carboplatin, Avastin, Avastin + chemotherapy, PCV, Nitrosurea."

Subsequently, the second level Appeals and Grievance determination letter was issued to the provider accordingly upholding the first level review on October 27, 2014.

6. Sunshine determined that there is insufficient medical literature to assess the Novo TTF-100A's safety and health outcomes for patient management. Sunshine concluded that the therapy is investigational and experimental. Medicaid rule prohibits the provision of services which are investigational or experimental in nature.

CONCLUSIONS OF LAW

7. By agreement between the AHCA and the Department of Children and Families, AHCA has conveyed jurisdiction to the Office of Appeal Hearings to conduct this hearing pursuant to § 120.80, Fla. Stat.

8. This is a final order pursuant to Fla. Stat. § 120.569 and § 120.57.

9. This hearing was held as a de novo proceeding pursuant to Fla. Admin. Code R. 65-2.056.

10. In accordance with Fla. Admin. Code R. 65-2.060(1), the burden of proof was assigned to the petitioner.

11. The standard of proof in an administrative hearing is by a preponderance of the evidence (See Fla. Admin. Code R. 65-2.060(1)). The preponderance of the evidence standard requires proof by "the greater weight of the evidence," (Black's Law Dictionary at 1201, 7th Ed.).

12. The Florida Medicaid program is authorized by Fla. Stat. Chapter 409 and Fla. Admin. Code Chapter 59G. The Medicaid program is administered by the Agency.

13. All Medicaid goods and services must be medically necessary. The definition of medically necessary is found in Fla. Admin. Code R. 59G-1.010 and states:

> (166) 'Medically necessary' or 'medical necessity' means that the medical or allied care, goods, or services furnished or ordered must:
> (a) Meet the following conditions:
> 1. Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain;
> 2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patient's needs;
> **3. Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational;** (emphasis added)
> 4. Be reflective of the level of service that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available; statewide; and
> 5. Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider...
> . . .
>
> (c) The fact that a provider has prescribed, recommended, or approved medical or allied care, goods, or services does not, in itself, make such care, goods or services medically necessary or a medical necessity or a covered service.

14. The cited rule sets forth that medical necessity means the medical or allied care, goods, or services furnished or ordered must meet the following five conditions; one of those conditions is that the service must be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational.

15. Sunshine denied the petitioner's request for a Novo TTF-100A device to treat his brain cancer. To date there has been one published clinical trial. The trial concluded that there is negligible difference between results using the Novo TTF-100A and results using standard care methods (chemotherapy, radiation, surgery). The Novo TTF-100A has not achieved main stream acceptance in the medical community because there is insufficient medical literature regarding its safety and effectiveness. Sunshine concluded that the device is experimental and investigational and is not a medical necessity as the term is defined in the Florida Administrative Code.

16. After carefully reviewing the evidence and controlling legal authorities, the undersigned concludes that the respondent's decision in this matter was correct. The petitioner did not prove by a preponderance of the evidence that the Novo TTF-100A is medically necessary to allow payment by the Medicaid Program.

DECISION

Based on the forgoing Findings and Facts and Conclusions of Law, the appeal is denied.

NOTICE OF RIGHT TO APPEAL

This decision is final and binding on the part of the agency. If the petitioner disagrees with this decision, the petitioner may seek a judicial review. To begin the judicial review, the petitioner must file one copy of a "Notice of Appeal" with the Agency Clerk, Agency for Health Care Administration, 2727 Mahan Drive, Tallahassee, FL 32308-5403. The petitioner must also file another copy of the "Notice of Appeal" with the appropriate District Court of Appeal. The Notices must be filed within thirty (30) days of the date stamped on the first page of the final order. The petitioner must either pay the court fees required by law or seek an order of indigency to waive those fees. The petitioner is responsible for any financial obligations incurred as the agency has no funds to assist in this review.

DONE and ORDERED this 16th day of February, 2015,

in Tallahassee, Florida.

Leslie Green
Hearing Officer
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Copies Furnished To [redacted] Petitioner
Marilyn Schlott, Area 3, AHCA Field Office Manager