STATE OF FLORIDA
AGENCY FOR HEALTH CARE ADMINISTRATION
OFFICE OF FAIR HEARINGS

FILED
Sep 09, 2024, 4:31 pm
OFFICE OF FAIR HEARINGS

[redacted],

PETITIONER,

vs.

CHILDREN'S MEDICAL SERVICES,

RESPONDENT.
_____/

AHCA Case No.: 24-FH1727
Plan ID No.: [redacted]

FINAL ORDER

Pursuant to notice, the undersigned Hearing Officer convened a telephonic Fair Hearing on the instant case on July 9, 2024, at 10:02 p.m. Eastern Standard Time ("EST").

APPEARANCES

For the Petitioner: [redacted], CTO & Co-Founder
[redacted]
Petitioner's Authorized Representative

For the Respondent: [redacted],
Regulatory Research Coordinator
Children's Medical Services

STATEMENT OF ISSUE

The issue is whether Petitioner proved by a preponderance of the evidence that Respondent's denial of Durable Medical Equipment ("DME"), namely a [redacted], Myocycle Functional Electrical Stimulation Cycle System was incorrect.

PRELIMINARY STATEMENT

All parties appeared for the Fair Hearing telephonically. [redacted], the Chief Technology Officer and Co-Founder of [redacted] ("[redacted]") appeared as the Petitioner's

Designated Authorized Representative at the Fair Hearing and testified on behalf of the Petitioner. Nichole Vega ("Ms. Vega"), Regulatory Research Coordinator for Children's Medical Services ("CMS" or "Respondent") appeared at the Fair Hearing as a representative for Respondent. Dr. Mai Fung, M.D. ("Dr. Fung"), Medical Director for CMS and Nicholas Crosby, Therapy advisor appeared as a witnesses for the Respondent. The following personnel of CMS attended the Fair Hearing for observation purposes only; Samira Jean-Louis, Occupation Therapist; Eloisa Arriaga, Case Manager, Lynn Garguilo, Supervisor of Case Management, and Amy Sheffield, Case Manager. In addition, Joanne White, Ombudsman, and Elyssa Luke, Esq., both from the Florida Department of Health appeared at the Fair Hearing for observational purposes.

Chrissy Simmons, Medical/Healthcare Program Analyst and Fair Hearing Liaison for the Agency for Health Care Administration ("Agency" or "AHCA") appeared for the Fair Hearing as an observer.

Prior to the Fair Hearing, Respondent sent to the Office of Fair Hearings and Petitioner a two hundred and sixty-five (265)-page evidence package that was admitted into evidence without objection, is identified as "Respondent's Composite Exhibit 1", and is maintained in the Office of Fair Hearings' document management system as "Segment 001 MFH Packet [Petitioner].pdf", and "Segment 002 MFH Packet [Petitioner].pdf". The Petitioner did not submit any exhibits into evidence.

FINDINGS OF FACT

1. The Petitioner became an enrolled member of CMS as of October 1, 2021. *See* Respondent's Composite Exhibit 1, page 2. CMS is a managed care organization contracted by the Agency to provide services to eligible Medicaid recipients in the state of Florida.

2. As of the date of the Fair Hearing, Petitioner is [redacted] *See* Respondent's Composite Exhibit 1, page 47 and *Testimony of* [redacted].

3. On March 19, 2024, the Petitioner submitted a request for a Myocycle Functional Electrical Stimulation ("FES") Cycling Therapy System under the miscellaneous Health Care Common Procedure Coding System ("HCPCS") Durable Medical Equipment Code of E1399. *See* Respondent's Composite Exhibit 1, page 4. The MyoCycle is a prescription only, Class II medical device that is intended for the prevention or retardation of muscle atrophy, the relaxation of muscle spasms, and muscle re-education that can be used at home by people with lower-limb paralysis. *See* Respondent's Composite Exhibit 1, page 13. On March 26, 2024, CMS issued a Notice of Adverse Benefit Determination ("NABD") denying Petitioner's request for the Myocycle FES Cycling Therapy System based on medical necessity. Respondent's Composite Exhibit 1, pages 4-9 The NABD explained the denial of Petitioner's requested Myocycle FES Cycling System in pertinent part:

> We made our decision because:
> *(Check all boxes that apply)*
>
> __**X**__ We determined that your requested services are **not medically necessary** because the services do not meet the reason(s) checked below: *(See Rule 59G-1.010)*
> ____ Must be needed to protect life, prevent significant illness or disability, or alleviate severe pain.

__**X**__ Must be individualized, specific, consistent with symptoms or diagnosis of illness or injury and not be in excess of the patient's needs.
____ Must meet accepted medical standards and not be experimental or investigational.
____ Must be able to be 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.
____ Must be furnished in a manner not primarily intended for convenience of the recipient, caretaker, or provider.
(The convenience factor is not applied to the determination of the medically necessary level of private duty nursing (PDN) for children under the age of 21.)

____ The requested **service is not a covered benefit**.

____ **Other authority** .
. . .
The facts that we used to make our decision are: Centene Clinical Policy: Durable Medical Equipment and Orthotics and Prosthetics Guidelines, CP.MP.107 and Florida Medicaid Durable Medical Equipment and Medical Supply Services Coverage and Limitations Handbook. This decision was made with regards to Early and Periodic Screening, Diagnostic and Treatment Services (EPSDT).

Rationale: Request for E1399 (durable medical equipment miscellaneous) has been carefully reviewed but cannot be approved at this time due to lack of demonstrated medical necessity. The requested item, MyoCycle FES Cycling Therapy System, is not considered durable medical equipment (DME). The requested equipment will not protect life, prevent significant illness or significant disability, or alleviate severe pain. Furthermore, it will not correct or ameliorate defects and physical illnesses or conditions that the member currently exhibits. Please discuss other possible funding options for this item with your child's therapy provider or primary care doctor.

Id.

4. On April 12, 2024, the Petitioner requested a plan appeal regarding the denial of the requested Myocycle FES Cycling Therapy System. *See* Respondent's Composite Exhibit 1, page 71. On May 9, 2024, CMS issued a Notice of Plan Appeal Resolution ("NPAR") upholding the denial of Petitioner's request for the Myocycle FES Cycling Therapy System. *See* Respondent's Composite Exhibit 1, pages 71-74. The NPAR states the following explanation, in pertinent part:

> The facts that we used to make our decision are: the previous denial to authorize a MyoCycle (cycle to help you with [redacted]) is upheld. The requested equipment will not protect life, prevent significant illness or significant disability, or alleviate severe pain. Furthermore, it will not correct or reduce defects and physical illnesses or conditions that the member currently exhibits. This device is not durable medical equipment. It is not medically necessary to complete activities of daily living (bathing, toileting, feeding). Outside funding sources would be appropriate in this case. The reasons for this decision are based on a set of standards. This included DME and O&P Criteria Reference Number: CP.MP.107; Sunshine Health Member Handbook, Services covered by Sunshine Health and the Florida State Medicaid DME fee schedule. This decision was made with regards to EPSDT (Early and Periodic, Screening, Diagnosis and Treatment (EPSDT) Requirements in the Managed Medical Assistance Program).

Id.

5. On May 21, 2024, the Petitioner requested a Fair Hearing regarding the denial of the Myocycle FES Cycling Therapy System. On June 21, 2024, the undersigned Hearing Officer issued a notice to all parties of record scheduling the Fair Hearing to be conducted by telephone on July 9, 2024, at 10:00 a.m. EST.

6. The Centene Corporation Clinical Policy for Durable Medical Equipment and Orthotics and Prosthetics Guidelines (Reference Number CP.MP.107, June 2022) states in-part as follows:

> **Policy/Criteria**
> **1.** It is the policy of health plans affiliated with Centene Corporation® that durable medical equipment, orthotics, and prosthetics are **medically necessary** when the general and applicable equipment-specific criteria in A and B are met:
> A. **General criteria:** Both of the following have been provided to the member/enrollee and/or caregiver, as applicable:
> 1. Education regarding use of the device, with demonstrated understanding;
> 2. A trial of the requested device, with demonstrated ability to use it safely and effectively.

See Respondent's Composite Exhibit 1, page 242.

7. The Petitioner's Authorized Representative is the Chief Technology Officer and co-founder of [redacted], the manufacturer of the Myocycle FES Cycling Therapy System. [redacted]

[redacted] testified that the 2021 article in Evidence presents "Level 1" evidence that use of the Myocycle would be beneficial to the Petitioner. *See* Respondent's Composite Exhibit 1, pages 48-63. [redacted] testified that the Myocycle FES Cycling Therapy System ameliorates the secondary conditions of [redacted] and will protect life plus will relieve the Petitioner's pain.

8. Dr. Fung testified for the Respondent that there is no evidence in the file that the Petitioner had successfully trialed the Myocycle FES Cycling Therapy System and was not aware if Medicaid had approved the Myocycle for use by other Medicaid recipient's. Dr. Fung further testified there is insufficient evidence that the Myocycle device protects life and reduces pain, that there is low quality evidence that the device would benefit the Petitioner, and that there is no "Level 1" evidence that the Myocycle improves muscles.

9. Nicholas Crosby, a therapy advisor for the Respondent, testified that he is not familiar with the Petitioner, and that he is unaware whether he is obtaining physical therapy or occupational therapy.

10. On March 2, 2024, [redacted], M.D. provided a prescription to the Petitioner for the Myocycle FES Cycling Therapy System, stating [redacted] opinion that the benefits of the Petitioner's use of the Myocycle FES Cycling Therapy System outweigh any risk to the Petitioner. *See* Respondent's Composite Exhibit 1, page 47.

CONCLUSIONS OF LAW

11. The Agency's Office of Fair Hearings has jurisdiction over the subject matter of this proceeding and the parties pursuant to section 409.285(2) of the Florida Statutes (2019). This order is the final administrative decision of AHCA under Fla. Stat. § 409.285(2)(a).

12. This hearing was held as a *de novo* proceeding pursuant to Florida Administrative Code Rule ("Fla. Admin. Code R.") 59G-1.100(17)(b).

13. The burden of proof in this proceeding is governed by Fla. Admin. Code R. 59G-1.100(17)(g), which provides as follows:

> The burden of proof is on the party asserting the affirmative of an issue, except as otherwise required by statute. The burden of proof is on the Agency or plan, whichever is applicable, when the issue presented is the suspension, reduction, or termination of a previously authorized service. The burden of proof is on the recipient or enrollee when the issue presented is the denial or a limited authorization of a service. The party with the burden of proof shall establish its position to the satisfaction of the Hearing Officer by a preponderance of the evidence.

14. Because Petitioner is requesting a new service, Fla. Admin. Code R. 59G-1.100(17)(g) assigns the burden of proof to Petitioner. The standard of proof in an administrative hearing is a preponderance of the evidence. The preponderance of the evidence standard requires proof by "the greater weight of the evidence" (Black's Law Dictionary at 1201, 7th Ed.).

15. States must provide Early and Periodic Screening, Diagnostic, and Treatment ("EPSDT") services to Medicaid-eligible children under age 21 when requested under the Medicaid state plan. *See* 42 U.S.C. § 1396a(a)(43); 42 U.S.C. § 1396d(a)(4).

16. According to 42 U.S.C. § 1396d(r)(5), EPSDT services mean, in relevant part, the following items and services:

> Such other necessary health care, diagnostic services, treatment, and other measures described in subsection (a) of this section to correct or ameliorate defects and physical and mental illness and conditions discovered by the screen services, whether or not such services are covered under the state plan.

17. A state may place medical necessity limitations on EPSDT services. *See* 42 C.F.R. §§ 440.230(a), (b), (d).

18. Section 409.905(2), Florida Statutes, limits EPSDT services with a medical necessity standard:

> The [Agency] shall pay for early and periodic screening and diagnosis of a recipient under age 21 to ascertain physical and mental problems and conditions and all services determined by the agency to be medically necessary for the treatment, correction, or amelioration of these problems and conditions, including personal care, private duty nursing, durable medical equipment, physical therapy, occupational therapy, speech therapy, respiratory therapy, and immunizations.

19. The Petitioner's requests for DME, namely a Myocycle FES Cycling Therapy System are governed by the Florida Medicaid Durable Medical Equipment and Medical Supply Services Coverage Policy: Wheelchairs, Hospital Beds, and Ambulatory Aid (December 2023) ("DME Policy"), which is incorporated by reference in Fla. Admin. Code R. 59G-4.070. The DME Policy provides the following, in pertinent part:

> **1.0 Introduction**
> Florida Medicaid wheelchairs, hospital beds, and ambulatory aids durable medical equipment and medical supply (DME) services provide medically necessary equipment or supplies to assist, correct, or improve mobility of eligible recipients.
> . . .
> **1.1 Florida Medicaid Policies**
> This policy is intended for use by providers that render wheelchairs, hospital beds, and ambulatory aids DME services to eligible Florida Medicaid recipients. It must be used in conjunction with Florida Medicaid's General Policies (as defined in section 1.3) and any applicable service-specific and claim reimbursement policies with which providers must comply.
> . . .
> **1.2 Statewide Medicaid Managed Care Plans**
> Florida Medicaid managed care plans must comply with the service coverage requirements outlined in this policy, unless otherwise specified in the AHCA contract with the Florida Medicaid managed care plan. The provision of services to recipients enrolled in a Florida Medicaid managed care plan must not be subject to more stringent service coverage limits than specified in Florida Medicaid policies.
> **1.4 Definitions**
> . . .
> **1.4.5 Medically Necessary/Medical necessity**
> As defined in Rule 59G-1.010, F.A.C.

. . .

2.2 Eligible Recipient

2.1 General Criteria

An eligible recipient must be enrolled in the Florida Medicaid program on the date of service and meet the criteria provided in this policy. Provider(s) must verify each recipient's eligibility each time a service is rendered.

2.2 Who Can Receive

Florida Medicaid recipients requiring medically necessary wheelchairs, hospital beds, and ambulatory aids DME services. **Some services may be subject to additional coverage criteria as specified in section 4.0.**

. . .

4.0 Coverage Information

4.1 General Criteria

Florida Medicaid covers services that meet all of the following:

- Are determined medically necessary
- Do not duplicate another service
- Meet the criteria as specified in this policy

4.2 Specific Criteria

Florida Medicaid covers wheelchairs, hospital beds, and ambulatory aids DME in accordance with the American Medical Association's Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS), and the applicable Florida Medicaid fee schedule(s), or as specified in this policy.

Florida Medicaid covers custom and specialized equipment when a less costly alternative is not available to fulfill the recipient's need.

. . .

4.3 Early and Periodic Screening, Diagnosis, and Treatment

As required by federal law, Florida Medicaid provides services to eligible recipients under the age of 21 years, if such services are medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness. Included are diagnostic services, treatment, equipment, supplies, and other measures described in section 1905(a) of the SSA, codified in Title 42 of the United States Code 1396d(a). As such, services for recipients under the age of 21 years exceeding the coverage described within this policy or the associated fee schedule may be approved, if medically necessary. For more information, please refer to Florida Medicaid's Authorization Requirements Policy.

5.0 Exclusion

5.1 General Non-Covered Criteria

Services related to this policy are not covered when any of the following apply:

- The service does not meet the medical necessity criteria listed in section 1.0
- The recipient does not meet the eligibility requirements listed in section 2.0
- The service unnecessarily duplicates another provider's service

. . .

7.0 Authorization

7.1 General Criteria

The authorization information described below is applicable to the fee-for-service delivery system. For more information on general authorization requirements, please refer to Florida Medicaid's Authorization Requirements Policy.

7.2 Specific Criteria

Providers must obtain authorization from the quality improvement organization (QIO) as follows:

- **For miscellaneous procedure codes**
- **When indicated on the applicable Florida Medicaid fee schedule(s)**

. . .

8.3.1 Customized Equipment

Providers must include a non-classified procedure code for customized equipment on the claim form.

. . .

8.4 Diagnosis Code

Providers must report the most current and appropriate diagnosis code to the highest level of specificity that supports medical necessity, as appropriate for this service.

Respondent's Composite Exhibit 1 at pages 86-93 (emphasis added).

20. Petitioner's request for DME is also governed by the Florida Medicaid Durable Medical Equipment and Medical Supply Services Provider Fee Schedule for All Medicaid Recipients 2024 ("DME Fee Schedule"). The Fee Schedule states that healthcare Common Procedure Coding System (HCPCS) billing code D1399 is governed by a medical necessity limitation. See DME Fee Schedule at page 47.

20. The Florida Medicaid Definitions Policy (August 2017), incorporated by reference in Fla. Admin. Code R. 59G-1.010, provides definitions of commonly used terms that are applicable to all sections of Rule Division 59G, Florida Administrative Code (F.A.C.), unless specifically stated otherwise in a service-specific coverage policy or rule. The Florida Medicaid Definitions Policy defines "Medically Necessary" or "Medical Necessity" as follows:

> The medical or allied care, goods, or services furnished or ordered must meet the following conditions:

- Be necessary to protect life, to prevent significant illness or significant disability, or to alleviate pain
- **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**
- Be consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational
- 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
- Be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider

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.

(Emphasis added).

21. The Petitioner requested DME and more specifically a Myocycle FES Cycling Therapy System. *See* supra ¶ 3. In the NABD and in the NPAR, Respondent denied Petitioner's request for the Myocycle FES Cycling Therapy System as not medically necessary, that the Myocycle is not considered durable medical equipment, that the Myocycle will not protect life, prevent significant illness or significant disability, or alleviate severe pain, and that the Myocycle will not correct or ameliorate the Petitioner's defects and physical illnesses or conditions. *See* supra ¶¶ 3, 4, and 8. This medical necessity requirement is referenced in the EPSDT guidelines, the Respondent's Durable Medical Equipment Policy, CP.MP.107, and the Florida Medicaid Definitions Policy. *See* supra ¶ ¶ 6, 18 and 21.

22. As Petitioner bears the burden of proof, Petitioner must show that Respondent's decision was incorrect. *See* supra ¶ ¶ 13 and 14. Thus, Petitioner must demonstrate by a preponderance of the evidence that the Myocycle FES Cycling Therapy System is "…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", that it will protect life, prevent significant illness or significant disability, or alleviate severe pain, and that the Myocycle will correct or ameliorate the Petitioner's defects and physical illnesses or conditions.. *See* supra ¶ ¶ 18, 19 and 21.

23. The Respondent's Medical Director, Dr. Fung provided credible testimony that there is no evidence in the file that the Petitioner had successfully trialed the Myocycle FES Cycling Therapy System, or that there is sufficient evidence that the Myocycle device protects life and reduces pain, that there is low quality evidence that the device would benefit the Petitioner, or that the Myocycle will not correct or ameliorate the Petitioner's defects and physical illnesses or conditions. *See* supra ¶ 8.

20. In this case, [redacted], M.D. provided a prescription to the Petitioner for the Myocycle FES Cycling Therapy System, stating [redacted] opinion that the benefits of the Petitioner's use of the Myocycle FES Cycling Therapy System outweigh any risk to the Petitioner. *See* supra ¶ 10. However, section 2.83 of the Definitions Policy mandates that "[t]he 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." *See* supra ¶ 21. Therefore, the Written Order from [redacted], M.D. does not in itself make the requested Myocycle FES Cycling Therapy System medically necessary.

24. In this case, Petitioner did not establish that by a preponderance of the evidence that a Myocycle FES Cycling Therapy System was 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. The undersigned Hearing Officer finds that Petitioner did not establish that the Myocycle

FES Cycling Therapy System meets the Respondent's criteria or the Florida Medicaid program's criteria, and the requested DME is medically necessary.

25. Based on the totality of the circumstances, evidence, testimony, the Durable Medical Equipment Fee Schedule, and the applicable Florida policies, the Petitioner has not established that the Myocycle FES Cycling Therapy System is medically necessary under Florida Medicaid and Respondent's Clinical Guidelines. Looking at all the evidence relevant to the particular needs of Petitioner, Petitioner has not demonstrated that the requested DME is necessary to correct or ameliorate a defect or a physical and mental illness or condition. Therefore, the undersigned Hearing Officer concludes that Petitioner did not prove by a preponderance of the evidence that Respondent's decision to deny the requested Myocycle FES Cycling Therapy System was incorrect.

IT IS THEREFORE ORDERED AND ADJUDGED:

Respondent's denial of the requested Myocycle FES Cycling Therapy System is hereby **AFFIRMED**. Petitioner's appeal based on Respondent's denial is hereby **DENIED**.

DONE and ORDERED this 9th day of September, 2024, in Tallahassee, Leon County, Florida.

Alan J. Leifer
24-FH1727
2024.09.09
10:13:02 -04'00'

ALAN J. LEIFER, Hearing Officer
Agency for Health Care Administration
Office of Fair Hearings
2727 Mahan Drive, Mail Stop # 11
Tallahassee, FL 32308-5407

NOTICE OF A RIGHT TO JUDICIAL REVIEW

A PARTY WHO IS ADVERSELY AFFECTED BY THIS FINAL ORDER IS ENTITLED TO JUDICIAL REVIEW, WHICH SHALL BE INSTITUTED BY FILING THE ORIGINAL NOTICE OF APPEAL WITH THE AGENCY CLERK OF AHCA, AND A COPY, ALONG WITH THE FILING FEE PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE AGENCY MAINTAINS ITS HEADQUARTERS OR WHERE A PARTY RESIDES. REVIEW PROCEEDINGS SHALL BE CONDUCTED IN ACCORDANCE WITH THE FLORIDA APPELLATE RULES. THE NOTICE OF APPEAL MUST BE FILED WITHIN 30 DAYS OF THE RENDITION OF THE ORDER TO BE REVIEWED.

Copies Furnished To:

[redacted]

Children's Medical Services
CMSPlanContract@flhealth.gov

AHCA Medicaid Hearing Unit
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