

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



FILED

Feb 02, 2023, 10:01 am

OFFICE OF FAIR HEARINGS

[REDACTED],

PETITIONER,

AHCA Case No.: 22-FH1466

Plan ID No.: [REDACTED]

vs.

HUMANA MEDICAL PLAN, INC.,

RESPONDENT.

_____ /

FINAL ORDER

Pursuant to notice, the undersigned convened a telephonic Fair Hearing in this matter on November 21, 2022, at 1:22 p.m. Eastern Standard Time ("EST").

APPEARANCES

For the Petitioner:

[REDACTED]

Petitioner's Authorized Representative

For the Respondent:

Michael Moens
Grievance and Appeals Specialist
Humana Medical Plan, Inc.

STATEMENT OF ISSUE

The issue is whether Petitioner proved by a preponderance of the evidence that Respondent's decision to deny Petitioner's request for custom cranial remolding orthoses (helmet) was incorrect.

PRELIMINARY STATEMENT

All parties appeared telephonically. [REDACTED] (“[REDACTED]”), Petitioner’s Authorized Representative and [REDACTED], appeared and provided testimony on behalf of Petitioner.

Michael Moens, Grievance and Appeals Specialist for Humana Medical Plan, Inc. (“Humana” or “Respondent”), appeared as a representative on behalf of Respondent. Dr. Ann Brady (“Dr. Brady”), Medical Director for Humana, appeared as a witness for Respondent. Dr. Lorena Aliaga Deza (“Dr. Aliaga”), Medical Director for Humana, appeared as a witness for Humana. Katrina Ali with Humana appeared as an observer.

Doris Rivera, Medical Health Care Program Analyst with the Agency for Health Care Administration (“Agency” or “AHCA”), appeared as an observer on behalf of the Agency.

Interpreter Anna, Translator ID number 400984, provided translator services for Petitioner.

Petitioner did not introduce any exhibits at the Fair Hearing. Prior to hearing Respondent sent to the Office of Fair Hearings and Petitioner a three hundred and eighty-five (385)-page evidence packet. The packet appears in the Office of Fair Hearings case management system as “Evidence Packet 22-FH1466_Part1.pdf,” “Evidence Packet 22-FH1466_Part2.pdf,” and “Evidence Packet 22-FH1466_Part3.pdf.” Absent an objection from Petitioner, the undersigned admitted Respondent’s packet into evidence as Respondent’s Composite Exhibit 1.

FINDINGS OF FACT

1. Petitioner is an enrolled member of Humana, which is a managed care organization contracted by the Agency to provide services to eligible Medicaid recipients in Florida.

2. Petitioner is a [REDACTED] ([REDACTED] year old [REDACTED]. See Respondent's Composite Exhibit 1 at 41. Petitioner is diagnosed with [REDACTED] ([REDACTED]). *Id.* at 28, 42.

3. In well care notes dated [REDACTED], Petitioner's physician, Dr. Liza Ayuso, diagnosed Petitioner with [REDACTED]. *Id.* at 41. Dr. Ayuso's notes indicate the following plan: plastic surgeon evaluation, make sure to reposition Petitioner more towards [REDACTED] right side, frequent tummy time, place baby more on baby chairs and exersaucer [sic] to avoid pressure on the back of [REDACTED] head, and hold baby up more. *Id.* at 42.

4. On June 13, 2022, Petitioner's provider, Dr. Eric Stelnicki ("Dr. Stelnicki") of [REDACTED] [REDACTED], requested prior authorization for a cranial remolding helmet. *Id.* at 26, 29. The helmet is a non-invasive device used to correct the symmetry of an infant's skull. *Id.* at 30. The preauthorization request indicated that Petitioner was "repositioned/treated with conservative PT, home exercise, and parent education with environmental changes for 5 months . . . Measurements noted [REDACTED] [REDACTED]

[REDACTED] Black and white pictures were faxed to Humana with the preauthorization request. *Id.* at 31, 54-58. Dr. Stelnicki noted that Petitioner's measurements reveal "asymmetry of measurement [REDACTED] which is well above two standards of deviation from the norm for a which his/her age." *Id.* at 52-53.

5. On June 21, 2022, Respondent issued a Notice of Adverse Benefit Determination ("NABD") denying Petitioner's request for a cranial remolding helmet. *Id.* at 4-8. The NABD stated the basis for the denial as follows:

We determined that the requested services were not medically necessary because the services do not meet either of the reason(s) checked below: (*See Rule*)

X Must be individualized, specific, consistent with symptoms or diagnosis of illness or injury and not be in excess of the patient's needs.

The facts that we used to make our decision are: We received a request for your child to have a custom cranial remolding orthosis (Special helmet to fix the shape of your child's head.) The medical records provided by your child's doctor were reviewed and did not show that it is medically necessary for your child to have this special helmet. Your child's medical records show that they have a problem with



In order for this special helmet to be approved, your child would need to have all of the following:

- Helmet is ordered by a specialist (orthopedic or craniofacial surgeon)
- Measurements of your child's head support a moderate to severe deformity
- Color pictures of your child's head taken from the top, front, back, and right and left sides
- A letter or statement from your child's specialist noting that your child needs this helmet to fix the shape of their head
- 6 months of documentation noting repositioning exercises (laying your child on different sides and tummy) have not improved the shape of your child's head

Your child's medical records were reviewed. Your child's medical records do not show color pictures of your child's head taken from the top, front, back, and right and left sides and 6 months of documentation noting repositioning exercises (laying your child on different sides and tummy) have not improved the shape of your child's head. The medical records received do not support that it is medically necessary for your child to have this special helmet. Please discuss this letter with your child's doctor to help get the care that is needed.

This decision was made by a Humana physician based on:

- The definition of medical necessity as defined in Chapter 59G-1.010(2.83) Florida Administrative Code
- Florida Durable Medical Equipment and Medical Supply Services Coverage and Limitations Handbook, section titled: Custom Cranial Remolding Orthosis, section titled: Eligibility and Reimbursement Requirements

Id. at 5-8.

6. Petitioner requested a plan appeal and received a Notice of Plan Appeal Resolution ("NPAR") dated July 28, 2022, upholding the denial. *Id.* at 19-22. The NPAR explained as follows:

On June 29, 2022 we received your timely plan appeal request regarding Humana Medical Plan's Notice of Adverse Benefit Determination dated June 21, 2022, 158448966, denying the authorization for a custom cranial remolding orthosis (helmet) to be provided to [Petitioner].

On July 22, 2022, after consideration of the information you provided to Humana Healthy Horizons in support of your plan appeal, was reviewed by a medical director who is a DO and board certified in Family Medicine and Osteopathic Manipulative Treatment, hereby denies your plan appeal.

The reason for the decision is the request is not medically necessary. You have requested that we approve a custom cranial remolding orthosis (helmet) for your child, for a diagnosis of [REDACTED]. We have reviewed the information provided by your child's doctor. The measurements of your child's head were also reviewed. In order for a helmet to be approved we need records that show ALL of the following:

- Helmet is needed to fix the shape of the head and face, AND
- Prescribed by a specialist (an orthopedic or craniofacial surgeon); AND
- Measurements of your child's head support a moderate to severe deformity, AND
- Color pictures of your child's head taken from the top, front, back, and right and left side, AND
- A letter or statement from the specialist physician saying that your child need this helmet, AND
- Six months of documented repositioning exercises (laying on different sides and on your tummy have not improved the shape)

The information provided did not include ALL of the items listed above. Your child's records did not show:

- Color pictures of your child's head taken from the top, front, back, and right and left side, AND
- Six months of documented repositioning exercises (laying on different sides and on your tummy have not improved the shape)

The information received does not support that it is medically necessary for your child to receive a helmet. Please contact your child's primary care physician to discuss this further and obtain the care you are requesting for your child.

This decision was based on the definition of medical necessity as defined in Chapter 59G-1.010 (2.83) Florida Administrative Code and Florida Medicaid Durable Medical equipment and Medical Supply Coverage and Limitations Handbook section titled: Custom Cranial Remolding Orthosis.

Id. at 18-19.

7. Petitioner requested a Fair Hearing on August 2, 2022. The Office of Fair Hearing (“Office”) issued a Scheduling Order on October 19, 2022, which scheduled the hearing for November 21, 2022, at 1:00 p.m. Eastern Standard Time, and all parties were notified.

8. At hearing, ██████████ asserted that Humana denied the helmet because they considered it to be requested for a “cosmetic” purpose. ██████ testified that Petitioner’s head is ██████████ and that Petitioner’s need for the helmet is medical rather than “cosmetic.” Ms. Parades asserted that Petitioner’s clinic provided color photos to Humana. Petitioner provided no exhibits or photos at the Fair Hearing.

9. At the hearing, Dr. Aliaga testified that at the time of the review, the clinical documentation did not support Petitioner’s request. The measurement submitted show that Petitioner’s ██████████ is ██████████. *Id.* at 33. No color pictures of the Petitioner’s head were provided. *Id.* Finally, the documentation did not show that Petitioner was repositioned for six months and that it had failed to improve the shape of the child’s head. *Id.* Dr. Brady testified that color photos and new measurements would need to be submitted to support a severe deformity.

CONCLUSIONS OF LAW

10. 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), Florida Statutes. This order is the final administrative decision of AHCA under section 409.285(2)(a), Florida Statutes.

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

12. Because Petitioner is requesting a new service, Fla. Admin. Code R. 59-1.100(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.).

13. 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). 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.

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

15. Petitioner is a Medicaid recipient who is under [REDACTED] years of age. Thus, the provisions of the EPSDT program apply to the request for a cranial remolding helmet in this case.

16. The DME Handbook, incorporated by reference in Fla. Admin. Code R. 59G-4.070, governs requested DME services available under Florida Medicaid. The DME Handbook provides the following:

Durable Medical Equipment (DME): Durable medical equipment (DME) is defined as medically-necessary equipment that can withstand repeated use, serves a medical purpose, and is appropriate for use in the recipient’s home as determined by the Agency for Health Care Administration (AHCA).

...

Services Limited to Recipients Under 21 Years of Age:

Many durable medical equipment (DME) items and services are limited to recipients under 21 years of age.

To determine whether a service is available to all recipients or limited to recipients under age 21 years of age, refer to the DME and Medical Supply Services Provider Fee Schedules and the specific requirements described in this handbook.

...

Service Criteria:

All DME medical supplies, and orthotics and prosthetic devices must be:

- Medically necessary, and
- Functionally appropriate for the individual recipient, and
- Adequate for the intended medical purpose, and
- For conventional use, and
- For the exclusive use of the recipient.

DME items requested or supplied must not duplicate or perform the same function as other DME equipment or medical supplies currently in the recipient’s possession.

...

Reimbursement Information:

The Medicaid fee reimbursed for durable medical equipment (DME) and medical supplies including labor, travel, delivery, shipping, handling, fees for measuring, casting, fitting, adjusting or dispensing items or products.

...

Introduction

The DME and Medical Supply Services Provider Fee Schedules are tables of columns listing the Medicaid reimbursable Healthcare Common Procedure Coding System (HCPCS) Level II Procedure Codes, their descriptors, and other information pertinent to each code.

...

Fee Schedules

The DME and Medical Supply Services Provider Fee Schedule for All Medicaid Recipients lists the DME and medical supplies covered for all Medicaid recipients, regardless of age.

...

**Custom Cranial Remolding Orthosis
Description**

A custom Cranial remolding orthosis is a non-invasive device used to correct the symmetry of an infant's skull.

Eligibility and Reimbursement Requirements

Custom cranial remolding orthoses require prior authorization (PA). PA requests must be submitted using the appropriate DME procedure code, to ensure proper routing for physician review.

Custom cranial remolding orthotic devices are covered by Medicaid when it is determined medically necessary to correct a moderate to severe craniofacial deformity. Supporting documentation, at a minimum, must include:

- A prescription from an orthopedic or craniofacial surgeon; and
- Clinical evidence, including measurements, indicating the infant's current cranial index of symmetry (CIS) is >83; and
- Current color photographs of the infant's head, taken from the following views:
 - Superior;
 - Frontal;
 - Posterior;
 - Right and left lateral; and
- A statement from a treating orthopedic or craniofacial surgeon, stating that treatment using a cranial remolding orthosis is recommended due to poor improvement in the infant's CIS, after a documented six (6) months trial period of active counter positioning has been completed; and
- Six (6) month's worth of documentation regarding daily counter positioning therapy.

17. Section 2.83 of the Definitions Policy, incorporated by reference into Fla. Admin. Code R.

59G-1.010, 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 severe 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.

18. In the instant case, Petitioner requested a cranial remolding helmet. *See supra* ¶ 5, 6. As established on the record by the evidence and testimony, Respondent denied Petitioner's request, because the documentation submitted in support of Petitioner's request failed to establish that the requested helmet is medically necessary. *See supra* ¶ 5, 6.

19. The DME Policy provides that Florida Medicaid reimburses for services that do not duplicate another provider's service and are determined to be medically necessary. *See supra* ¶ 16. Pursuant to section 2.83 of the Definitions Policy, the five (5) conditions of medical necessity must be met in order for "medical or allied care, goods, or services furnished or ordered" to be determined medically necessary. *See supra* ¶ 17. Accordingly, all five (5) of the conditions must be met in order for Respondent to approve requested DME services.

20. The record shows that Respondent correctly denied Petitioner's request for a cranial remolding helmet. Specifically, the DME Policy requires the following: a prescription from an orthopedic or craniofacial surgeon; and clinical evidence, including measurements, indicating the infant's current cranial index of symmetry (CIS) is >83; and current color photographs of the infant's head (taken from superior, frontal, posterior, and right and left lateral views); and a statement from a treating orthopedic or craniofacial surgeon, stating that treatment using a cranial remolding orthosis is recommended due to poor improvement in the infant's CIS, after a documented six (6) months trial period of active counter positioning has been completed; and

six (6) month's worth of documentation regarding daily counter positioning therapy. *See supra* ¶ 16. As established by Dr. Brady, the record is devoid of the required clinical index of symmetry of >83, color photographs of the Petitioner's head, and documentation showing that Petitioner was repositioned for six months that it had failed to improve the shape of the child's head. Given that Petitioner did not submit the required documentation, Petitioner's request fails to satisfy the requirements set forth in the DME Policy. Therefore, Petitioner failed to meet their burden of establishing that Respondent's denial of Petitioner's request for a helmet was incorrect.

21. Appurtenant to this matter, section 2.83 of the Definitions Policy mandates that "[t]he medical or allied care, goods, or services furnished or ordered must . . . [b]e 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." *See supra* ¶ 17. Given that Petitioner failed to establish that the requested cranial remolding helmet is warranted in this matter, *supra* ¶ 20, the requested helmet is "in excess of [Petitioner's] needs." *See supra* ¶ 17. Accordingly, Petitioner did not establish that the requested helmet is medically necessary.

22. ██████████ relied upon Dr. Stelnick's recommendation to show that the helmet was medically necessary. However, 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. *See supra* ¶17.


23. Looking at all of the evidence relevant to the particular needs of Petitioner, Petitioner did not demonstrate that the requested helmet at issue in this case is necessary "health care, diagnostic services, treatment, and other measures . . . to correct or ameliorate defects and physical and mental illness and conditions discovered by the screen services." In light of the both

parties' testimony, Respondent's Composite Exhibit 1, the DME Policy, and the Definitions Policy, the undersigned finds that Petitioner did not prove by a preponderance of the evidence that Respondent's denial of the requested helmet was incorrect.

IT IS HEREBY ORDERED AND ADJUDGED THAT:

Respondent's denial of Petitioner's request for a custom cranial remolding orthoses (helmet) is **AFFIRMED**. Petitioner's appeal based on Respondent's denial of a custom cranial remolding orthoses (helmet) is **DENIED**.

DONE and **ORDERED** this 2nd day of February 2023, in Tallahassee, Leon County, Florida.

Laura Gallagher
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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:



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