

FILED

MAY 30 2023

Agency For Health
Care Administration

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

[REDACTED],

PETITIONER,

AHCA Case No.: 23-FH0330

Plan ID No.: [REDACTED]

vs.

MOLINA HEALTH CARE OF FLORIDA, INC.,

RESPONDENT.

_____ /

FINAL ORDER

Pursuant to notice, the undersigned Hearing Officer convened a telephonic Fair Hearing in the instant case on April 26, 2023, at 12:00 p.m. Eastern Standard Time ("EST").

APPEARANCES

For the Petitioner:

[REDACTED]

Authorized Representative

For the Respondent:

Caridad Bello

Government Contract Specialist

Molina Health Care of Florida, Inc.

STATEMENT OF ISSUE

The issue is whether Petitioner proved by a preponderance of the evidence that Respondent's denial of the prescription drug [REDACTED] was incorrect.

PRELIMINARY STATEMENT

All parties appeared for the Fair Hearing telephonically. [REDACTED] (“[REDACTED]”), Petitioner’s Authorized Representative and [REDACTED], appeared for the Fair Hearing to provide testimony on behalf of Petitioner and did not call any witnesses.

Caridad Bello, Government Contract Specialist for Molina Health Care of Florida, Inc. (“Molina”), appeared for the Fair Hearing as representative for Respondent. The following persons appeared for the Fair Hearing as a witness for Respondent: Dr. Lenny Pham (“Dr. Pham”), Clinical Pharmacy Manager for Molina, and Shauna Lowden, a Clinical Pharmacist for Molina.

Marielisa Amador, Medical Health Care Program Analyst for the Agency for Health Care Administration (“Agency” or “AHCA”), appeared for the Fair Hearing as an observer.

Petitioner did not introduce any exhibits at the Fair Hearing. Prior to the Fair Hearing, Respondent sent to the Office of Fair Hearings (“Office”) and Petitioner a fifty-two (52)-page evidence packet, which was admitted into evidence a Respondent’s Composite Exhibit 1. Respondent’s Composite Exhibit 1 includes the following documents: a cover sheet; a prior authorization form; various medical records; a Notice of Adverse Benefit Determination (“NABD”) (dated December 30, 2022); Prior Authorization Criteria for [REDACTED] [REDACTED] Treatment; a Plan Appeal Acknowledgement; and a Notice of Plan Appeal Resolution (“NPAR”) (dated January 19, 2023).

FINDINGS OF FACT

1. Petitioner is an enrolled member of Molina. See Respondent’s Composite Exhibit 1, pages 1-2, 39. Molina 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]. *Id.* at 3. Petitioner provider is [REDACTED] (“[REDACTED]”) of [REDACTED]. *Id.* at 3. [REDACTED] requested approval for [REDACTED]. *Id.* at 3. [REDACTED] recommended this drug to treat Petitioner’s [REDACTED]. *Id.* Petitioner is [REDACTED].

Id.

3. On December 30 2022, Molina issued a NABD denying Petitioner’s request for [REDACTED] based on medical necessity. *Id.* at 24-28. The NABD explained the basis of the denial as follows, in pertinent part:

Molina Healthcare of Florida, Inc. has reviewed your request for [REDACTED] [REDACTED], which we received on 12/29/2022 1:41:36 PM. After our review, this service has been:

DENIED as of 12/30/2022 9:03:09 AM

We made our decision because:

- Other authority: Criteria Not Met

The facts that we used to make our decision are: This request ([REDACTED] [REDACTED]) to treat your health condition ([REDACTED]) is not approved. Molina Healthcare has looked at your drug records and the notes your doctor sent.

The following rules in the guidelines were not met: Your doctor must show you not growing as expected (height standard deviation score {SOS} greater than 2 standard deviations {SD} below the mean for age and gender OR height less than the 5th percentile for age and gender). Your doctor must show that your bone age is delayed (bone age minimum of one year behind chronological age). Your doctor must show you have a low level of [REDACTED] (ONE of the following: {A} 2 [REDACTED] {GH} stimulation tests producing peak concentration less than 10 nanograms per milliliter {ng/ml},, {B} 1 GH stimulation test producing peak GH less than 10 ng/ml AND a defined central nervous system pathology {such as empty sella syndrome}, history of irradiation, multiple pituitary hormone deficiency, or a genetic defect affecting the GH axis, {C} 1 GH stimulation test producing peak GH less than 10 ng/ml AND IGF-1 and/or IGFBP-3 are below a

clearly normal range).Your doctor must have ruled out or treated other causes of your problem (Idiopathic Short Stature (ISS) has been ruled out).Your doctor must have ruled out or treated other causes of your problem (example., hypothyroidism, chronic ischemic disease).

Please talk to your provider about your health care options.

{NOTE TO PROVIDER: Each prior authorization request should include all necessary clinical notes, lab work, and medication history. Please see the formulary at www.molinahealthcare.com. The preferred options may require clinical review. Florida Medicaid Criteria used for review: [REDACTED] Treatment in Children and Adults}

Respondent's Composite Exhibit 1, pages 24-28.

4. On January 4, 2023, Petitioner requested a plan appeal. *Id.* at 39. On January 19, 2023, Molina issued an NPAR upholding the denial of [REDACTED]. *Id.* at 48-50. The NPAR states the following, in pertinent part:

On January 5, 2023, after consideration of the information you provided to Molina Healthcare of Florida in support of your plan appeal, Molina Healthcare of Florida hereby denies your plan appeal. As a result, [Petitioner] will not receive the drug [REDACTED]. The decision was made by the Molina Healthcare of Florida Chief Medical Officer, an Internal Medicine Physician.

The reason for our decision was based on the Florida Agency for Health Care Administration Criteria for [REDACTED] Treatment in Children and Adults. It shows rules that you have to meet for the drug [REDACTED] to be approved. The rules state that your doctor must show you not growing as expected (height standard deviation score {SDS} greater than 2 standard deviations {SD} below the mean for age and gender or height less than the 5th percentile for age and gender), Your doctor must show that your bone age is delayed (bone age lowest of one year behind chronological age), and your doctor must show you have a low level of [REDACTED].

Your notes from [REDACTED] do not meet the rules. The notes sent show you are in the [REDACTED], and you must be below the 5th percentile to meet. Your bone age is [REDACTED], and you [REDACTED] (rules calls for 2). For this reason, your request for the use of the drug [REDACTED] is not approved. Please talk to your doctor about your health care options.

Respondent's Composite Exhibit 1, pages 29-30.

5. On February 16, 2023, [REDACTED] requested a Fair Hearing on behalf of Petitioner regarding the denial of [REDACTED]. On April 3, 2023, the undersigned Hearing Officer issued a Scheduling Order, to all parties of record, scheduling the Fair Hearing to be convened by telephone on April 26, 2023, at 12:00 p.m. EST.

6. [REDACTED] testified that Petitioner is requesting authorization for [REDACTED] treatment due to [REDACTED]'s concern for Petitioner's "growth velocity;" specifically, the rate at which Petitioner is growing. [REDACTED] asserts that Petitioner has a unique case, where [REDACTED] are needed. [REDACTED] bases [REDACTED] assessment on the height of Petitioner's family members when they were [REDACTED] age, and that the Petitioner is the shortest student in [REDACTED] class. [REDACTED] asserted that Petitioner has a new diagnosis of [REDACTED]; however, [REDACTED] did not provide medical records to support the diagnosis. [REDACTED] also argued that Petitioner's height is no longer in the [REDACTED] as the medical records on file are from [REDACTED], and there have been changes in Petitioner's case since that time.

7. Dr. Pham testified that Molina followed AHCA's Pharmacy Policy, which governs requests for [REDACTED] treatment for children. Dr. Pham reviewed the documents in Respondent's Composite Exhibit 1 and concluded that Petitioner did not meet the requisite criteria, *supra* ¶ 8, as Petitioner's bone age ([REDACTED]) is within normal limits of Petitioner's age at the time of the assessment ([REDACTED]). Petitioner's medical records indicate that Petitioner's height is close to the [REDACTED]^h [REDACTED]. Also, Petitioner's bone age is [REDACTED]. As a result, Molina determined that Petitioner's request was not medically necessary because Petitioner did not meet the required prior authorization criteria.

8. The internal criteria that Molina used to make its decision appears in the Agency's Prior Authorization Criteria for Pharmacy Policy ([REDACTED] Treatment in Children and Adults), which provides as follows, in pertinent part:

GROWTH HORMONE TREATMENT IN CHILDREN and ADULTS

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA FOR CHILDREN:

Required for Approval:

- Must have approved diagnosis with supporting documentation (if the preferred product listed below is FDA indicated, trial of the preferred product is required)
- ...
- Must be 16 years of age or younger
- Must be prescribed by an endocrinologist, pediatric endocrinologist, or pediatric nephrologist
- ...

**Pediatric Growth Hormone Deficiency ([REDACTED]):
Genotropin®, Norditropin®**

Growth velocity: < 5 cm/year

Present height: ≥ 2 standard deviations (SD) below the mean for age and gender or less than the 5th percentile for age and gender

Bone age: Minimum of one year behind chronological age Epiphyses: Confirmation of open growth plates if age 10 and older Diagnostic Evaluation (one of the following):

- **Two** subnormal responses to GH provocation tests (e.g., arginine, clonidine, glucagon, insulin and levodopa): Confirmation of stimulation test(s) with peak serum GH concentration less than 10 ng/ml; or
- **One** abnormal GH test is sufficient and the patient has defined CNS pathology, multiple pituitary hormone deficiency (MPHD), history of irradiation, or a genetic defect affecting the GH axis; or
- **One** subnormal response to a GH provocation test with peak serum GH concentration less than 10ng/ml) plus subnormal serum levels of insulin-like growth factor 1 (IGF-1) and/or insulin-like growth factor binding protein 3 (IGFBP3)

Exclusionary Conditions:

- **Idiopathic Short Stature (JSS) has been ruled out (normal birth weight and GH sufficient)**
- Other pituitary hormone deficiencies (e.g. hypothyroidism, chronic ischemic disease) have been ruled out

Respondent's Composite Exhibit 1, page 30-31.

CONCLUSIONS OF LAW

9. The Agency's Office has jurisdiction over the subject matter of this proceeding and the parties pursuant to section 409.285(2), Florida Statutes (2022). This order is the final administrative decision of AHCA under section 409.285(2)(a).

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

11. 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.).

12. Petitioner's request for prescription drug services is governed by the Florida Medicaid Prescribed Drugs Services Coverage Policy (December 2017) ("PD Policy"), which is incorporated by reference in Fla. Admin. Code R. 59G-4.250. The Prescribed Drug Policy provides the following, in pertinent part:

1.0 Introduction

1.1 Description

This policy describes Florida Medicaid's coverage of outpatient prescription drugs.

1.1.1 Florida Medicaid Policies

This policy is intended for use by providers that render prescribed drug 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.

Note: All Florida Medicaid policies are promulgated in Rule Division 59G, Florida Administrative Code (F.A.C.). Coverage policies are available on the Agency for Health Care Administration's (AHCA) Web site at <http://ahca.myflorida.com/Medicaid/review/index.shtml>.

1.1.2 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.

...

1.3 Definitions

The following definitions are applicable to this policy. For additional definitions that are applicable to all sections of Rule Division 59G, F.A.C., please refer to the Florida Medicaid definitions policy.

1.3.4 Medically Necessary/Medical Necessity

As defined in Rule 59G-1.010, F.A.C.

...

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 up to a 34-day supply of drugs, per prescription, in accordance with section 409.912, F.S., or as specified in this policy when prescribed by a licensed practitioner, for the following:

- Drugs on the PDL and published on the AHCA Web site at http://www.ahca.myflorida.com/medicaid/Policy_and_Quality/Policy/pharmacy_policy/index.shtml.
- Drugs prescribed for off-label use when included in the compendia referenced in section 1927(k)(6) of the SSA.
- Drugs that are not on the PDL.

The Agency for Health Care Administration determines the feasibility of adding a drug recommended by the Pharmaceutical and Therapeutics Committee to the PDL based on an assessment of the drug's cost-effectiveness, clinical efficacy, and safety.

...

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 General Policies on authorization requirements.

PD Policy at pages 1-5.

13. Because Petitioner is under the age of 21 years, the requirements of Early and Periodic Screening, Diagnostic, and Treatment ("EPSDT") apply. According to 42 U.S.C. § 1396d(r)(5), EPSDT services mean, in relevant part, the following items and services:

(3) Prescribed Drug services

(A) which are provided –

(i) at intervals which meet reasonable standards of dental practice, as determined by the State after consultation with recognized dental organizations involved in child health care, and

(ii) at such other intervals, indicated as medically necessary, to determine the existence of a suspected illness or condition; and

(B) which shall at a minimum include relief of pain and infections, restoration of teeth, and maintenance of dental health.

Further, according to 42 U.S.C. § 1396d(r)(5), EPSDT include, 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. The Florida Medicaid Definitions Policy (August 2017) ("Definitions Policy"), incorporated by reference in Fla. Admin. Code R. 59G-1.010, defines "Medically Necessary" or "Medical Necessity" as follows:

2.83 Medically Necessary or Medical Necessity

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.

Definitions Policy at page 7.

19. In the instant case, Petitioner requested the prescription drug [REDACTED] to treat [REDACTED] [REDACTED] [REDACTED] ([REDACTED]). See supra ¶ 2. As established by the evidence and testimony, Respondent denied Petitioner's request because the documentation submitted in support of Petitioner's Request failed to establish that Petitioner met the criteria for [REDACTED]. See supra ¶ 3-4.

20. Section 4.1 of the PD Policy provides that Florida Medicaid covers services that: are medically necessary; do not duplicate another service; and meet the criteria as specified in the PD Policy. See supra ¶ 12. The Florida Medicaid program covers prescription drugs that are determined to be medically necessary. See supra ¶ 12. The prescription drug must meet the medical necessity criteria set forth by section 2.83 of the Florida Medicaid Definitions Policy. See supra ¶ 18. The fact that a provider has prescribed and recommended a prescription drug does not, in itself, make such services medically necessary. See supra ¶ 18.

21. The testimony and evidence presented in this case reflects that Respondent's denial of [REDACTED] was warranted under the circumstances of this case, as Petitioner failed to meet medical necessity criteria as outlined in Fla. Admin. Code R. 59G0-1.010. Specifically, the request for [REDACTED] failed to meet the third criteria of medical necessity, which requires that the requested services must meet "generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational." See supra ¶ 18. The Agency's PD Policy for [REDACTED] provides the criteria for pediatric use of [REDACTED] for [REDACTED]. See supra ¶ 8. Specifically, the PD Policy regarding Pediatric [REDACTED] ([REDACTED]) for [REDACTED]® requires: (1) Growth velocity: < 5 cm/year – Present height: ≥ 2 standard deviations (SD) below the mean for age and gender or less than the 5th percentile for age and gender; and (2) Bone age: Minimum of one year behind chronological age Epiphyses: Confirmation of open growth plates if age 10 and older Diagnostic Evaluation. *Id.* Here, Dr. Pham provided credible and persuasive testimony as a pharmacist that Petitioner does not meet either criterion. See supra ¶ 8. Petitioner's growth velocity *is not* less than the 5th percentile for age and gender. See supra ¶ 2, 8. Petitioner's bone age *is not* a minimum of one year behind chronological age. See supra ¶ 2, 8. Therefore, the undersigned concludes that the request does not meet the PD Policy criteria.

22. As Petitioner bears the burden of proof, Petitioner must show by a preponderance of the evidence that Respondent's decision was incorrect. Here, Petitioner did not establish that the Petitioner meets the PD Policy criteria for pediatric [REDACTED]. There is no evidence in the record that Petitioner's growth velocity is less than the 5th percentile and Petitioner's bone age is at minimum a year behind their chronological age. [REDACTED] presented credible testimony that Petitioner is shorter than family members and classmates. See supra ¶ 7.

The undersigned considered [REDACTED]'s testimony and the provider's recommendation but applied more weight to Dr. Pham's testimony with regard to the requisite criteria.

23. Upon consideration of the testimony provided, Respondent's Composite Exhibit 1, and applicable law and policies, the undersigned Hearing Officer concludes that Petitioner did not prove by a preponderance of the evidence that the requested services meet the Prescribed Drug Policy criteria as required by section 4.1 of the policy. *See supra* ¶ 12. Because the request did not meet PD Policy criteria, the request is not consistent with generally accepted professional medical standards as determined by the Medicaid program. Therefore, the request is not medically necessary. Looking at all the evidence relevant to the particular needs of Petitioner, Petitioner has not shown that the requested services are necessary to provide "relief of pain and infections, restoration of teeth, and maintenance of dental health" or to correct or ameliorate a defect or a physical and mental illness or condition. Accordingly, the undersigned finds that Petitioner has not proved by a preponderance of the evidence that Respondent's denial of the prescription drug [REDACTED] was incorrect.

IT IS THEREFORE ORDERED AND ADJUDGED:

Respondent's denial of the prescription drug [REDACTED] is hereby **AFFIRMED**.
Petitioner's appeal based on Respondent's denial is hereby **DENIED**.

DONE and ORDERED this 30th day of May, 2023, in Tallahassee, Leon County, Florida.



Per _____
LAURA GALLAGHER, 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]
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