

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

FILED

Dec 16, 2015

Office of Appeal Hearings
Dept. of Children and Families



APPEAL NO. 15F-05976

PETITIONER,

Vs.

CASE NO.

AGENCY FOR HEALTH CARE ADMINISTRATION
CIRCUIT: 15 Palm Beach
UNIT: AHCA

RESPONDENT.

_____ /

FINAL ORDER

Pursuant to notice, the undersigned convened a telephonic administrative hearing in the above-referenced matter on October 8, 2015, at 1:00 p.m.

APPEARANCES

For the Petitioner: [REDACTED] pro se.

For the Respondent: Lisa Sanchez, Senior Program Specialist, Agency for Health Care Administration (AHCA).

STATEMENT OF ISSUE

At issue is the Agency's action, through Sunshine Health, in denying prescription coverage for [REDACTED] and [REDACTED] on April 15, 2015 due to the petitioner not meeting the criteria for Stage 3 or Stage 4 [REDACTED]. The petitioner carries the burden of proving her case by a preponderance of the evidence.

PRELIMINARY STATEMENT

Present as a witness for the petitioner was [REDACTED] Pharmacist.

Present as witnesses for the Agency were Paula Daley, Grievance and Appeals Coordinator II; Jill Hanson, Pharmacist; Richard Plymel, Pharmacy Manager; and Dr. David Gilchrist, Medical Director, all with Sunshine Health.

Present as an observer was Stephanie Smith with Sunshine Health.

The respondent submitted into evidence Respondent Exhibit 1 through 3.

FINDINGS OF FACT

Based upon the oral and documentary evidence presented at the final hearing and on the entire proceeding, the following Findings of Fact are made:

1. The petitioner lives in [REDACTED] County, Florida and is a Managed Medical Assistance Program (MMA) recipient. Sunshine Health Plan is the managed care agency authorized by AHCA to provide Medicaid services. The petitioner has [REDACTED] based on her condition of [REDACTED]

2. On or about April 15, 2015, the petitioner's treating physician requested prior authorization for the drugs Sovaldi 400mg and Ribavirin 200mg. It should be noted that Ribavirin is a drug provided in conjunction with Sovaldi and is not a stand-alone drug.

3. On April 15, 2015, Sunshine Health denied this request and mailed a Notice of Action to the petitioner stating:

There was no evidence of stage 3 or 4 [REDACTED] in the clinical information provided. The APRI score provided was 0.522. Evidence of Stage 3 or 4 [REDACTED] is defined as: [REDACTED] confirming a MATAVIR score of F3 or F4; OR Transient elastography (Fibroscan) score > 9.5 kPa; OR FibroTest score of greater than or equal to 0.58; OR APRI score greater than 1.5; OR Radiological imaging consistent with [REDACTED]

(e.g., evidence of portal hypertension); OR Physical findings or clinical evidence consistent with [REDACTED] as attested by the prescribing physician.

4. The respondent's pharmacist witness indicated this decision was made after reviewing all of the medical information provided by the petitioner's treating physician and provider. She indicated that the decision was made by following AHCA criteria.

5. The petitioner meets stage 2, or F2, criteria for her level of [REDACTED]. This is not in dispute. The petitioner and her witness argued that the drugs denied are needed to enhance the petitioner's quality of life. The petitioner argued that she needs the drugs now as it will be too late for her when she reaches stage 4. She argued that she is the best candidate for the denied drugs as she has had interferon treatment and she does not have many options at this time. She argued her liver is already enlarged.

6. The respondent reiterated that the decision remains correct based on the AHCA criteria and the petitioner's current level of liver function. She also indicated that if the petitioner meets the criteria of F3 or F4, she can then be approved for Sovaldi.

CONCLUSIONS OF LAW

7. The Department of Children and Families, Office of Appeal Hearings has jurisdiction over the subject matter of this proceeding and the parties, pursuant to § 409.285, Fla. Stat. This order is the final administrative decision of the Department of Children and Families under § 409.285, Fla. Stat.

8. This proceeding is a de novo proceeding pursuant to Fla. Admin. Code R. 65-2.056.

9. In accordance with Fla. Admin. Code R. 65-2.060 (1), the party having the burden shall establish his/her position by a preponderance of the evidence, to the satisfaction of the hearing officer.

10. 42 C.F.R § 438.210 Coverage and authorization of services addresses the contractual requirements of agreements between states and managed care organizations and explains as follows:

(b) *Authorization of services.* For the processing of requests for initial and continuing authorizations of services, each contract must require—

...

(3) That any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.

11. Section 409.912 (8)(a), Florida Statutes states in relevant parts:

(14) The agency may require prior authorization for Medicaid-covered prescribed drugs. The agency may prior-authorize the use of a product:

- a. For an indication not approved in labeling;
- b. **To comply with certain clinical guidelines;** or
- c. If the product has the potential for overuse, misuse, or abuse.

The agency may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug. The agency shall post prior authorization, step-edit criteria and protocol, and updates to the list of drugs that are subject to prior authorization on the agency's Internet website within 21 days after the prior authorization and step-edit criteria and protocol and updates are approved by the agency.

12. Fla. Admin. Code R. 59G-1.010 states in part:

(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;
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;
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...

13. The Agency for Health Care Administration's Prior Authorization Criteria for Sovaldi to treat [REDACTED] (treatment naïve with or without [REDACTED] treatment experienced without [REDACTED] requires, among other criterion:

Documentation of concurrent (or planning to start) therapy with ribavirin and peg-interferon when starting SOVALDI for a 12-week duration

Evidence of Stage 3 or Stage 4 [REDACTED] including one of the following:

- Liver biopsy confirming a METAVIR score of F3 or F4; OR
- Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa; OR
- Fibro Test score of greater than or equal to 0.58; OR
- APRI score greater than 1.5; OR
- Radiological imaging consistent with [REDACTED] (e.g., evidence of portal hypertension); OR
- Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician.

14. As shown in the Findings of Fact, Sunshine Health denied the petitioner's request for Sovaldi and Ribavirin on April 15, 2015 due to not meeting the criteria for Stage 3 or Stage 4 [REDACTED]

15. For the case at hand, the petitioner has not presented evidence of Stage 3 or Stage 4 [REDACTED] nor has she demonstrated that she meets the requirements set forth in AHCA's Prior Authorization Criteria noted above. Since the petitioner does not meet the preauthorization requirements for the approval of Sovaldi or Ribavirin, the respondent correctly denied prescription coverage for these drugs.

16. After careful review of the evidence submitted and the relevant laws set forth above, the undersigned concludes the Agency's action to deny prescription coverage for Sovaldi and Ribavirin was proper, and the Petitioner's burden was not met.

DECISION

Based upon the foregoing Findings of Fact and Conclusions of Law, this appeal is denied and the Agency action affirmed.

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.

FINAL ORDER (Cont.)
15F-05976
PAGE -7

DONE and ORDERED this 16 day of December, 2015,
in Tallahassee, Florida.

Robert Akel

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Copies Furnished To: [REDACTED] Petitioner
Judy Jacobs, Area 7, AHCA Field Office

[REDACTED]
Beverly Smith, Esq.