

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

FILED

MAY 11 2015

OFFICE OF APPEAL HEARINGS
DEPT OF CHILDREN & FAMILIES

APPEAL NO. 15F-00630

PETITIONER,

Vs.

CASE NO.

AGENCY FOR HEALTH CARE ADMINISTRATION
CIRCUIT: 13 Hillsborough
UNIT: AHCA

RESPONDENT.

FINAL ORDER

Pursuant to notice, the undersigned convened a telephonic administrative hearing in the above-referenced matter on March 18, 2015 at 3:09 p.m.

APPEARANCES

For the Petitioner: [REDACTED] LPN, Infectious Disease Associates

For the Respondent: David Beaven, Agency for Health Care Administration

STATEMENT OF ISSUE

At issue is whether the Agency properly denied Petitioner's request for prescription medication Harvoni.

PRELIMINARY STATEMENT

The Agency for Healthcare Administration (AHCA or Agency) is responsible for administering Florida's Medicaid Program.

Petitioner was present and did not provide testimony. She was represented by a nurse at her treating physician's office. Serving as Respondent's witness was Susan

Williams, Senior Pharmacist with the Agency. Arlene Elliott, Pharmacy Policy Administrator with the Agency, was present but did not provide testimony.

Respondent submitted twelve exhibits, marked and entered as Respondent's Exhibits 1 through 12, into evidence. The hearing officer took administrative notice of Section 409.912, Florida Statutes (2014), Florida Administrative Code Rule 59G-4.250, and the Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook.

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. Petitioner is an adult female diagnosed with chronic Hepatitis C, Type 1a. She is seeing a specialist physician for her treatment, who suggested a medication called Harvoni. Petitioner's April 17, 2014, metavirus scores show the hepatic fibrosis, or liver scarring, that she has. The results show minimal scarring on her liver (F0-F1). See Respondent's Exhibit 7. A CT scan from July 3, 2014 indicated a normal liver, as well. See Respondent's Exhibit 6.
2. Petitioner's treating specialist submitted a preauthorization request to the Agency for Harvoni on December 3, 2014. The specialist provided clinical notes and lab results to support the preauthorization request.
3. The Agency reviewed the submitted documentation and denied the request. The denial notice dated December 3, 2014, stated that "[t]his patient does not meet the FL MED criteria for this medication due to lack of evidence of Stage 3 or Stage 4 hepatic fibrosis." It included an internet web address link to the detailed drug criteria and

preferred alternatives. See Respondent's Exhibit 9. In response to the denial, Petitioner requested a fair hearing.

4. The Agency sent another notice dated February 3, 2015. This notice contained the same reason and information as the prior notice, but suggested an alternative combination therapy for the specialist to consider for Petitioner's care. The alternative combination therapy drugs are Olysio, Ribavirin, and Peg-Intron. The Agency encouraged Petitioner's physician to submit a preauthorization request for this combination therapy "[i]f this is an appropriate option for this patient and this treatment regimen may be considered...." See Respondent's Exhibit 12. Petitioner's physician did not submit a preauthorization request for the combined therapy.

5. The Agency denied the preauthorization request for Harvoni because Petitioner's condition must meet certain criteria to be approved for that particular drug. Based on the Agency's review of Petitioner's medical records, her condition does not meet the specific criteria for Harvoni but it may meet criteria for the suggested alternative drug therapy.

6. Petitioner's physician is concerned about the potential side effects of the suggested alternative therapy, such as depression, fatigue, and lowered platelet count. Side effects could compromise Petitioner's ability to stay compliant with her treatments.

7. Petitioner has not tried any drug therapy yet. Her condition is "naïve." Harvoni is indicated as an acceptable treatment regimen for chronic Hepatitis Type 1a diagnosis.

CONCLUSIONS OF LAW

8. The Department of Children and Families Office of Appeal Hearings has jurisdiction over the subject matter of this proceeding and the parties, pursuant to Section 120.80, Florida Statutes.

9. Florida Medicaid State Plan is authorized by Chapter 409, Florida Statutes, and Chapter 59G, Florida Administrative Code. The program is administered by the Agency.

10. This hearing was held as a de novo proceeding pursuant to Florida Administrative Code Rule 65-2.056.

11. As this matter involves a request for a service approval, the burden of proof was assigned to the Petitioner pursuant to Florida Administrative Code Rule 65-2.060(1).

12. The standard of proof needed to be met for an administrative hearing is by a preponderance of the evidence, as provided by Florida Administrative Code Rule 65-2.060(1).

13. Section 409.912, Florida Statutes (2014) provides that AHCA shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. For prescription drugs, Sections 409.912(37)(a)(14) through 409.912(16), Florida Statutes (2014), are instructive. Pursuant to Section 409.912(37)(a)(14), "the agency may require prior authorization for Medicaid-covered prescribed drugs." Section 409.91195 describes how the Agency creates and maintains such a process.

14. The Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook (July 2014) ("The Handbook") is promulgated into law by Florida

Administrative Code Rule 59G-4.250. The Handbook echoes the information from the Florida Statutes.

15. The Agency has the authority to manage its prior authorization process, including establishing criteria for approval. It established specific criteria for Harvoni. The Medicaid drug criteria for Harvoni require at least Stage 3 or 4 hepatic fibrosis for approval. See Respondent's Exhibit 11. Petitioner's scores show her hepatic fibrosis is not that advanced, so she does not meet the established criteria for Harvoni.

16. Petitioner had the burden of proof in this case. Petitioner did not meet her burden of proof to show that this particular medication is medically necessary and that there are no clinically acceptable alternatives. She is encouraged to work with her physician and the Agency to find a medication that will meet her needs and can be approved.

17. After careful review of the evidence submitted and the relevant laws set forth above, the undersigned finds the Agency's action in this matter was correct.

DECISION

Based upon the foregoing Findings of Fact and Conclusions of Law, the Petitioner's appeal is hereby DENIED and Agency's action is 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.

DONE and ORDERED this 11th day of May, 2014,

in Tallahassee, Florida.


Danielle Murray
Hearing Officer

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