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

FILED
JUN 26 2015
OFFICE OF APPEAL HEARINGS
DEPT OF CHILDREN & FAMILIES

[redacted]

APPEAL NO. 15F-03221

PETITIONER,

Vs.

CASE NO.

AGENCY FOR HEALTH CARE ADMINISTRATION
CIRCUIT: 06 Pasco
UNIT: AHCA

RESPONDENT.
_____/

FINAL ORDER

Pursuant to notice, the undersigned convened a telephonic administrative hearing in the above-referenced matter on June 3, 2015 at 11:07 a.m.

APPEARANCES

For the Petitioner: [redacted] Petitioner

For the Respondent: Stephanie Lang, Registered Nurse Specialist
Agency for Health Care Administration

STATEMENT OF ISSUE

At issue is whether the Agency properly denied Petitioner's request for prescription medication Zofran (ondansetron) 8mg ODT at the 4 tablets/32mg per day dosage.

PRELIMINARY STATEMENT

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

Petitioner represented himself at the hearing. Serving as Respondent's witnesses were India Smith, Grievance and Appeals Coordinator with Sunshine Health, Donna Laber, RN Manager of Grievance and Appeals with Sunshine Health, and Jill Hansen, Pharmacist with Sunshine Health.

Respondent submitted ten exhibits, marked and entered as Respondent's Exhibits 1 through 10, into evidence. The hearing officer took administrative notice of Section 409.910, 409.962 through 409.965, and 409.973, Florida Statutes (2014), as well as Florida Administrative Code Rule 59G-1.001 and 1.010.

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 a 59-year-old adult male diagnosed with terminal cancer, pancreatitis, diabetes, and post-traumatic stress disorder, among other illnesses. He has frequent severe pancreatitis attacks that result in vomiting and hospitalizations. He is unable to go out into the community without a catch bag for fear of a vomiting episode in public. His biggest fear is having an attack during his sleep, vomiting, and choking on the vomit as he sleeps.

2. Petitioner's primary care physician submitted a preauthorization request to the Agency for Zofran (ondansetron) 8mg ODT at the 4 tablets/32mg per day dosage on February 5, 2015. The physician indicated the increased dose was due to the increase frequency of pancreatitis attacks.

3. Sunshine Health reviewed the preauthorization request and denied it by notice dated February 6, 2015. The notice denied the request because it exceeds the amount

recommended by the Food and Drug Administration (FDA) and standard medical practice. Specifically, the maximum recommended dose of this drug is 24mg per day. The plan limits the drug quantity to 2 tablets per day, or 60 tablets every 30 days. Respondent's Exhibit 2.

4. On February 23, 2015, Sunshine Health received an appeal request from Petitioner in response to the denial. Petitioner's gastroenterologist also faxed medical documentation to Sunshine Health on the same day. The gastroenterologist is not the provider that requested the medication. Respondent's Exhibits 5 and 6.

5. Sunshine Health denied the appeal by notice dated March 9, 2015. The reason given for the denial is the request exceeds the maximum allowable limit for the drug. Respondent's Exhibit 4.

6. Upon further review, Sunshine Health's pharmacist and Petitioner's gastroenterologist were concerned about side effects that could occur with such a high dose of this medication. Specifically, heart problems could arise. Sunshine Health encouraged care coordination between Petitioner's treating physicians.

7. Petitioner is not concerned with the possible side effects because he believes he will not survive long with his ailments, and this is to help his quality of life. He could not reach his cardiologist prior to the hearing, but is willing to take the associated risks with this medication because he considers it life critical.

PRINCIPLES OF LAW AND ANALYSIS

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. The Office of Appeal Hearings provided the parties with adequate notice of the administrative hearing.

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(14) through 409.912(16), Florida Statutes, are instructive. Regarding drugs that are not on the preferred drug list, the statute states as follows:

> 16. The agency shall implement a step-therapy prior authorization approval process for medications excluded from the preferred drug list. Medications listed on the preferred drug list must be used within the previous 12 months before the alternative medications that are not listed. The step-therapy prior authorization may require the prescriber to use the medications of a similar drug class or for a similar medical indication unless contraindicated in the Food and Drug Administration labeling. The trial period between the specified steps may vary according to the medical indication. The step-therapy approval process shall be developed in accordance with the committee as stated in s. 409.91195(7) and (8). A drug product may be approved without meeting the step-therapy prior

authorization criteria if the prescribing physician provides the agency with additional written medical or clinical documentation that the product is medically necessary because:

a. There is not a drug on the preferred drug list to treat the disease or medical condition which is an acceptable clinical alternative;

b. The alternatives have been ineffective in the treatment of the beneficiary's disease; or

c. Based on historic evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective, or the number of doses have been ineffective.

The agency shall work with the physician to determine the best alternative for the patient. The agency may adopt rules waiving the requirements for written clinical documentation for specific drugs in limited clinical situations.

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 Handbook states on page 2-4 that:

Products included on the PDL must be prescribed first unless the patient has previously used these products unsuccessfully or the prescriber submits documentation justifying the use of a non-PDL product.

16. Further, at 2-5, the Handbook states:

Approval of reimbursement for alternative medications that are not listed on the preferred drug list shall be considered if listed products have been tried without success within the previous twelve months....

A drug product may be approved without meeting the step-therapy prior authorization criteria if the prescribing physician provides the Agency with additional written medical or clinical documentation that the product is medically necessary because:

- There is not a drug on the preferred drug list which is an acceptable clinical alternative to treat the disease or medical condition; or
- The alternatives have been ineffective in the treatment of the beneficiary's disease; or
- Based on historic evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective; or
- The number of doses has been ineffective.

17. Page 2-7 of the Handbook discusses quantity limitations.

> Medicaid limits the quantity and number of refills that may be reimbursed for certain drug classes. Medicaid also limits reimbursement for certain drug classes to recipients based upon clinical considerations of the patient's age. A current list of drug limitations can be found on the Internet at: www.mymedicaid-florida.com . Click on Public Information for Providers, then Pharmacy, then Drug Limitations.

18. Petitioner's requested drug and per tablet dosage is on the preferred drug list, but his request would require provision of additional tablets. The maximum allowed amount is limited by the Agency to "Zofran (ondansetron)/ODT 4mg, 8mg Maximum of 60 tablets every 30 days."[1] The excess requested amount is therefore not considered on the preferred drug list. In order to exceed the maximum amount, Petitioner must show, through medical or clinical documentation, that the excess dose is medically necessary.

19. Although Petitioner testified that he does not have enough tablets to get by with his currently prescribed dosage, his medical documentation did not support the need or explain why he needs to exceed the maximum allowed amount. Additionally, Sunshine Health received conflicting information from Petitioner's providers as to whether this medication amount was appropriate.

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[1] The drug limitations list, updated April 30, 2015, is available online by following the directions in paragraph 17.

20. Petitioner is encouraged to work with his doctors to get medical documentation explaining his need for the higher dosage. He can submit the medical documentation to Respondent with a new authorization request for review.

21. 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 26th day of June, 2015,

in Tallahassee, Florida.

Danielle Murray
Hearing Officer
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Copies Furnished To: [redacted] Petitioner
Don Fuller, Area 5, AHCA Field Office Manager