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

[redacted]

APPEAL NO. 15F-08823

PETITIONER,

Vs.

AGENCY FOR HEALTH CARE ADMINISTRATION
CIRCUIT: 09 Osceola
UNIT: AHCA

RESPONDENT.
_____/

FINAL ORDER

Pursuant to notice, the undersigned convened a telephonic administrative hearing in the above-styled matter on December 8, 2015, 2015, at approximately 4:00 p.m.

APPEARANCES

Petitioner: [redacted]

For Respondent: Doretha Rouse
Registered Nurse Specialist
Agency for Health Care Administration

STATEMENT OF ISSUE

At issue is whether or not Respondent's denial of Petitioner's request for the drug [redacted] was correct. The burden of proof is assigned to Petitioner.

PRELIMINARY STATEMENT

Petitioner represented herself at the hearing. Respondent presented the following witnesses:

- Stephanie Shupe – Regulatory Research Coordinator - Staywell
- Lisa Hogan – Clinical Pharmacist, Senior Manager, Medicaid Appeals Department - Staywell
- Erika Hatchman – Pharmacy Appeals Manager - Staywell

Petitioner's Exhibits 1 and 2 were entered into evidence. Respondent's Exhibits 1 through 13 were entered into evidence. The record was held open for Respondent to submit additional evidence. Respondent submitted additional evidence, entered as Exhibit 14. The undersigned took administrative notice of the July 2012 Florida Medicaid Provider General Handbook.

FINDINGS OF FACT

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

1. Petitioner is a 57-year-old female. At all times relevant to this proceeding, Petitioner was eligible to receive Medicaid services.

2. Petitioner is enrolled with Staywell as her Managed Medical Assistance (MMA) plan.

3. Petitioner's medical conditions include:

- [redacted]

4. Petitioner currently takes approximately 20 different medications to treat her conditions. She stated the medications ruin her appetite and she doesn't eat, which makes her vomit because she can't take them on an empty stomach, but forces herself

to do so. She currently does not take any medication for nausea, although she sometimes drinks Alka-Seltzer. She said nothing works to treat the nausea, only [redacted].

5. Petitioner previously took [redacted] by paying for it herself and says she can no longer afford it. Petitioner claims [redacted] helps with several of her conditions and would allow her to take fewer medications, along with treating the nausea.

6. Petitioner is largely homebound due to her condition. She testified she only leaves her house for doctor appointments and to buy food, and it can take her several hours to get out of the house.

7. On September 25, 2015, Petitioner's physician submitted a request for the [redacted] in order to treat her nausea.

8. In a Notice of Action dated September 28, 2015, Staywell informed Petitioner of the denial of the prescription. The Notice of Action (Respondent's Exhibit 5) states:

> The request could not be approved. This drug is not approved by the Food and Drug Administration (FDA) to treat NAUSEA. It is only FDA approved for the treatment of anorexia associated with weight loss in patients with AIDS; and nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments in patients 18 years of age and older.
>
> The facts we used to make our decision are: The criteria are the Food and Drug Administration (FDA) manufacturer package insert for [redacted] 5 MG CAPSULE, AND Policy & Procedure C20RX150 which states WellCare only covers FDA approved indication(s).

9. Petitioner filed an appeal with Staywell on October 20, 2015. Staywell sent Petitioner an Appeal Denial Upheld Notice, dated November 4, 2015, stating the request was reviewed by a board-certified doctor who was not part of the original review. It further stated the doctor's findings were given to Staywell's Appeal Review Committee,

consisting of Medical Director(s) specializing in Internal Medicine, and Pharmacist(s). (Respondent's Exhibit 11). The denial of the [redacted] was upheld and Staywell said they would not pay for the medication.

10. AHCA maintains a Preferred Drug List ("PDL"). [redacted] is not on the PDL. Medications not on the PDL require prior authorization. AHCA requires specific criteria be met for approval of [redacted] (Marinol). AHCA posts the criteria for approval of [redacted] on the Internet at the address: ahca.myflorida.com/Medicaid/Prescribed_Drug/drug_criteria_pdf/Marinol_Criteria.pdf.

11. The review criteria lists two conditions for which [redacted] can be prescribed: (A) Anorexia due to AIDS, and (B) Treatment of refractory chemotherapy-induced nausea and vomiting. (Respondent's Exhibit 14). Petitioner does not have either of these conditions.

12. Pursuant to Staywell's contract with AHCA (Respondent's Exhibit 12), they are permitted, but are not required, to cover prescriptions when the Medicaid State Plan would not. Specifically, the contract states:

> The Managed Care Plan shall make available those drugs not on the PDL, when requested and approved, if the drugs on the PDL have been used in a step therapy sequence or when other medical documentation is provided. The Managed Care Plan may adopt the Medicaid prior authorization criteria posted on the Agency website, or develop its own criteria. Prior authorization, step-edit therapy protocols for PDL drugs may not be more restrictive than that used by the Agency as indicated in the Florida Statutes, the Florida Administrative Code, the Medicaid State Plan and those posted on the Agency website.

13. Ms. Hogan testified that Staywell looked in the drug compendia known as [redacted] to make an informed decision as to whether or not [redacted] is appropriate for treating

any of Petitioner's conditions. [redacted] lists labeled and off-labeled uses, dosing, age requirements, administration, and the effects on the body with a particular drug.

14. Ms. Hogan testified the off-label indications for [redacted] are spasticity related to [redacted], diagnosis of [redacted] and before or after a patient receives surgery. Petitioner does not meet any of these criteria. She recommended that Petitioner take a copy of the PDL with her to her doctor to discuss if there are any options available to her.

CONCLUSIONS OF LAW

15. By agreement between AHCA and the Department of Children and Families, the Office of Appeal Hearings has jurisdiction to conduct this hearing pursuant to § 120.80, Fla. Stat.

16. This hearing was held as a *de novo* proceeding, in accordance with Florida Administrative Code Rule 65-2.056.

17. This is a Final Order, pursuant to Sections 120.569 and 120.57, Fla. Stat.

18. 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.).

19. Legal authority governing the Florida Medicaid Program is found in Fla. Stat. Chapter 409, and in Chapter 59G of the Florida Administrative Code. Respondent, AHCA, is the single state agency that administers the Medicaid Program.

20. Section 409.912 of the Florida Statutes, entitled "Cost-effective purchasing of health care", states, in pertinent part:

> [AHCA] shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care.
> ....
>
> (8)(a) The agency shall implement a Medicaid prescribed-drug spending-control program that includes the following components:
> 1. A Medicaid preferred drug list, which shall be a listing of cost-effective therapeutic options recommended by the Medicaid Pharmacy and Therapeutics Committee established pursuant to s. 409.91195 and adopted by the agency for each therapeutic class on the preferred drug list. At the discretion of the committee, and when feasible, the preferred drug list should include at least two products in a therapeutic class. The agency may post the preferred drug list and updates to the list on an Internet website without following the rulemaking procedures of chapter 120.
> ....
>
> 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. For purposes of this subparagraph, the term "step-edit" means an automatic electronic review of certain medications subject to prior authorization.

21. The Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook, July 2014 ("Drug Handbook") is promulgated into law by Chapter 59G of the Florida Administrative Code.

22. Page 2-4 of the Drug Handbook states, in relevant part:

> The Preferred Drug List (PDL) is a listing of prescription products recommended by the Pharmaceutical and Therapeutics (P&T) Committee for consideration by AHCA as efficacious, safe, and cost effective choices when prescribing for Medicaid patients.
> ....

> 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.
> ....
>
> Non-PDL drugs may be approved for reimbursement upon prior authorization.

23. Page 2-2 of the Drug Handbook provides:

> To be reimbursed by Medicaid, a drug must be medically necessary and either (a) prescribed for **medically accepted indications and dosages found in the drug labeling or drug compendia**...or (b) prior authorized by a qualified clinical specialist approved by the Agency.... (emphasis added).

24. The definition of "medically necessary" is found in Fla. Admin. Code R.59G-1.010, which 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; and
> 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.

25. Section 409.912 of the Florida Statutes requires AHCA to create a PDL. [redacted] is not on the PDL and therefore requires prior authorization. AHCA's criteria for [redacted] are available on its website.

26. Petitioner does not meet the criteria fo[redacted] listed on AHCA's website, contained in Respondent's Exhibit 14. Staywell is allowed to approve a medication even if AHCA's review criteria are not met, per its contract, so long as it meets the medically accepted indications and dosages found in the drug labeling or drug compendia. Staywell researched Drugdex and found that [redacted] is not indicated for any of Petitioner's conditions.

27. Petitioner is encouraged to work with her physician and research the Preferred Drug List and AHCA drug criteria to see if a different medication can meet her needs.

DECISION

Based upon the foregoing, Petitioner's appeal is DENIED and the 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 15 day of January, 2016,

in Tallahassee, Florida.

Rick Zimmer

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Copies Furnished To: [redacted] Petitioner
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