



**State of Florida**  
**Department of Children and Families**

**Rick Scott**  
*Governor*

**Mike Carroll**  
*Secretary*

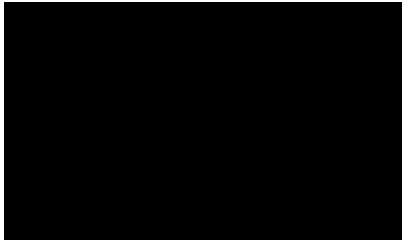
Date: 01/13/2016

To: Debbie Stokes, Area 4, AHCA Field Office Manager

From: Nathan Koch, Chief  
Office of Appeals Hearings

Subject: Final Order

RE:



The hearing request for the above individual has been completed and the final order is attached.

Please send correspondence to:  
Office of Appeal Hearings  
Building 5, Room 255  
1317 Winewood Blvd.  
Tallahassee, FL 32399-0700

The office telephone number is 850-488-1429, SC 278-1429.  
The fax number is 850-487-0662, SC 277-0662.

**FILED**

Jan 13, 2016

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

Office of Appeal Hearings  
Dept. of Children and Families

  
28945 SE 175 ST  
UMATILLA, FL 32784

APPEAL NO. 15F-09074

PETITIONER,

Vs.

AGENCY FOR HEALTH CARE ADMINISTRATION  
CIRCUIT: 05 Lake  
UNIT: AHCA

RESPONDENT.

**FINAL ORDER**

Pursuant to notice, the undersigned convened a telephonic administrative hearing in the above-styled matter on November 25, 2015, at approximately 1:30 p.m.

**APPEARANCES**

Petitioner:



For Respondent:

Selwyn Gossett  
Medical/Health Care Program Analyst  
Agency for Health Care Administration

**STATEMENT OF ISSUE**

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

**PRELIMINARY STATEMENT**

Petitioner represented himself at the hearing. The following individuals were present as witnesses for Respondent:

- Dr. Marc Kaprow – Medical Director, Long Term Care Plan Florida – United Healthcare
- Christian Laos – Senior Compliance Analyst – United Healthcare
- Shana Bush – Pharmacy Director – United Healthcare

Bonnie Taylor, Program Administrator with the Agency for Health Care Administration (“AHCA” or “Agency”) observed the hearing. Respondent’s Exhibits 1 through 11 were entered into evidence at the hearing. Petitioner did not move any exhibits into evidence at the hearing.

### **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 63-year-old male. At all times relevant to this proceeding, Petitioner was eligible to receive Medicaid services.
2. Petitioner is enrolled with United Healthcare (“United”) as his Managed Medical Assistance (MMA) plan.
3. Petitioner has a diagnosis of [REDACTED]. He previously tried [REDACTED] and [REDACTED] but they were unsuccessful in treating his condition.
4. Petitioner’s physician submitted a request to United for a 12-week course of the drug [REDACTED] on July 13, 2015. According to Petitioner’s physician, multiple trials of a 12-week course of [REDACTED] have shown it to be highly effective at treating [REDACTED] [REDACTED]
5. On July 14, 2015, United denied the prescription as not being medically necessary.

The Notice of Action (Respondent’s Exhibit 3) states:

The facts that we used to make our decision:

The requested medication is used for a virus when you have more severe [REDACTED]. The facts given to us do not show that you have [REDACTED]. This decision was made per the United Healthcare Community and State [REDACTED] medication guideline.

6. Petitioner filed an appeal with United, which was received on August 5, 2015. United issued a letter upholding the denial on September 4, 2015.

7. Petitioner's [REDACTED] which translates to [REDACTED] (Respondent's Exhibit 7). The fibrosis score range for [REDACTED]

[REDACTED] In order for the condition to be at [REDACTED] the fibrosis score needs to be [REDACTED]

8. AHCA maintains a Preferred Drug List ("PDL"). [REDACTED] is not on the PDL.

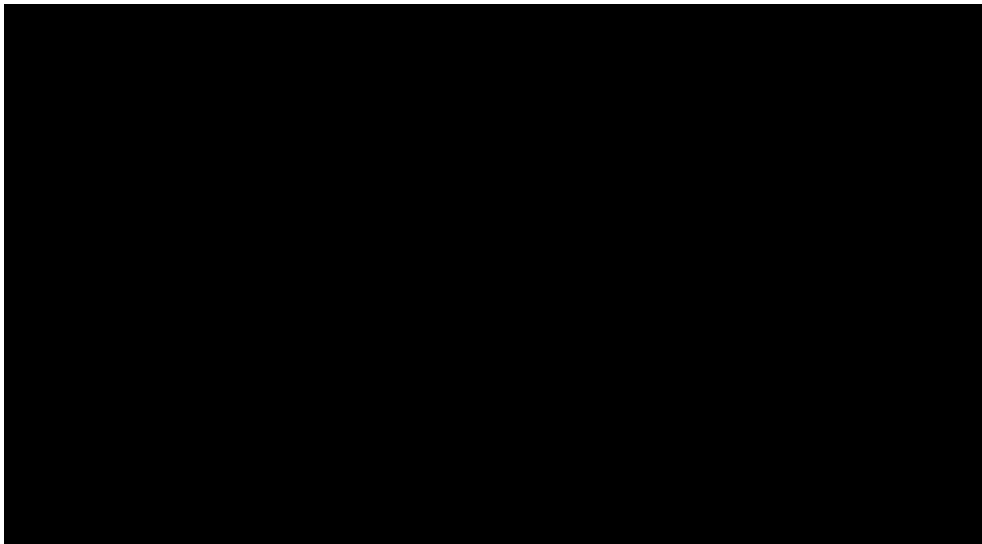
Medications not on the PDL require prior authorization. AHCA requires specific criteria be met for approval of [REDACTED]. AHCA posts the criteria for approval of [REDACTED] on the Internet at the address:

[ahca.myflorida.com/Medicaid/Prescribed\\_Drug/drug\\_criteria\\_pdf/Harvoni\\_Criteria.pdf](http://ahca.myflorida.com/Medicaid/Prescribed_Drug/drug_criteria_pdf/Harvoni_Criteria.pdf)

9. The specific criteria for Petitioner's condition are contained in the box titled "[REDACTED]"

[REDACTED] (Respondent's Exhibit 4). Dr. Kaprow testified this is the most common type of [REDACTED] in the United States. The criteria requires evidence of [REDACTED]

[REDACTED] including one of the following:



- Petitioner did not submit any evidence regarding this criterion.

10. Petitioner is currently asymptomatic. Petitioner said it didn't make any sense to him to wait for his condition to worsen before treating it. In a letter contained in Respondent's Exhibit 8, Petitioner's physician, a board certified gastroenterologist, stated: "recent reports [show] initiating therapy in patients with [REDACTED] may extend the benefits of sustained [REDACTED] (SVR)." He included medical literature with the letter to support this opinion, showing the [REDACTED] of [REDACTED]

11. Dr. Kaprow testified an individual only needs a portion of their [REDACTED] in order for it to function and that Petitioner's [REDACTED] is currently functioning. He also testified there is no guarantee that Petitioner's condition will worsen and that his lifestyle might keep it from worsening. He said [REDACTED] changes are seen before changes in liver function, so in the event Petitioner's condition increases to [REDACTED], he can likely treat the condition before he loses [REDACTED]. He further stated that [REDACTED] may or may not go away after treatment.

#### **CONCLUSIONS OF LAW**

12. 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.

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

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

15. 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, 7<sup>th</sup> Ed.).

16. 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.

17. 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.

18. 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.

19. 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.

20. 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....

21. 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.

22. Section 409.912 of the Florida Statutes requires AHCA to create a PDL. [REDACTED] is not on the PDL and therefore requires prior authorization. Respondent can publish the PDL and drug criteria on an Internet website and make changes without going through the rulemaking process, and has done so. Therefore, the undersigned is bound by the drug criteria for [REDACTED] listed in Respondent's Exhibit 4, as addressed above.

23. The evidence presented by Petitioner shows he has a [REDACTED] [REDACTED]. The drug criteria for [REDACTED] is clear that [REDACTED] [REDACTED] with a [REDACTED] is required in order for [REDACTED] to be approved.

24. It may be desirable to provide Petitioner with the [REDACTED] sooner, rather than later. Doing so might result in a significantly better outcome, as stated by Petitioner's board certified gastroenterologist, and supported by the supplied medical literature. However, the undersigned concludes Respondent properly applied the drug criteria for [REDACTED] in this matter, and the drug criteria has the force of law. Desirability does not equate with necessity, and it must be medically necessary, as defined in the Florida Administrative Code, in order for Petitioner to receive the [REDACTED]



25. Petitioner is encouraged to closely monitor his condition. In the event his condition worsens, he may wish to submit a new request for [REDACTED] at that time.

**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 13 day of January, 2016,  
in Tallahassee, Florida.

*Rick Zimmer*

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Rick Zimmer  
Hearing Officer  
Building 5, Room 255  
1317 Winewood Boulevard  
Tallahassee, FL 32399-0700  
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Email: Appeal.Hearings@myflfamilies.com

Copies Furnished To [REDACTED] Petitioner  
Debbie Stokes, Area 4, AHCA Field Office Manager