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

[redacted]

APPEAL NO. 15F-02143

PETITIONER,

Vs.

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 April 1, 2015 at 2:07 p.m.

APPEARANCES

For Petitioner: [redacted]
Petitioner's mother

For Respondent: Carol King
Registered Nurse Specialist

ISSUE

At issue is whether respondent's denial of lidocaine 5% adhesive patches (lidocaine patches) was proper.

PRELIMINARY STATEMENT

Petitioner was not present but represented by his mother. No exhibits were entered into evidence.

Ms. King appeared as both the representative and witness for the respondent. Present as witnesses from Molina Healthcare (Molina) were: Natalie Fernandez, Government Contract Specialist; Dr. Alfred Romay, Pharmacy Director; Margarita Quinones, Supervisor of Pharmacy Services; and Alexandra Rodriguez, Government Contract Specialist. Respondent's Exhibits "1" and "2" were accepted into evidence.

Administrative Notice was taken of Fla. Admin. Code R. 59G-1.010; 59G-4.250; Florida Statutes § 409.912; § 409.963; § 409.965: § 409.969; § 409.971; § 409.972; and § 409.973; the Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook (Drug Services Handbook); and the Florida Medicaid Preferred Drug List (PDL).

The record was held open through April 8, 2015 for respondent to provide chart notes from petitioner's treating physician; an updated PDL; and the meaning of PDL terminology "Auto PA for Select Diagnosis". Information was timely received and entered into evidence as Respondent's Exhibits "3" and "4". The record was held open through April 8, 2015 for petitioner to provide alternative prescription guidelines for lidocaine patches. A response was not received. The record was held open through April 15, 2015 for either party to respond to post hearing submissions. Responses were not received.

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 is an adult male with a birth date of [redacted] At all times relevant to this proceeding, petitioner was Medicaid eligible.

2. Petitioner's Medicaid services are through the Statewide Managed Medical Assistance (MMA) Program. Since October 1, 2014 Molina is the managed care entity providing petitioner's Medicaid services. Prior to that date, Magellan Complete Care was the MMA provider.

3. Due to a traumatic brain injury, bone ossification occurred in petitioner's hip. The ossification caused misalignment of his left ankle. To facilitate straightening of the ankle, pins were surgically inserted. The procedure caused ankle swelling and pain.

4 An encounter summary regarding a physician's appointment on January 23, 2015 identified the following medical conditions: left ankle pain; foot pain; anxiety; hypertensive disorder; deep venous thrombosis; oral infection; impotence; rash; edema of lower extremity; nausea; and injury of great toenail.

5. The above summary also referenced a decompressive craniotomy in August 2011.

6. To address petitioner's ankle/foot pain (code 729.5), the treatment plan called for lidocaine patches. One patch was to be worn each day for up to 12 hours.

7. A request for the lidocaine patches was then forwarded to Molina for a prior authorization review.

8. Molina must be in compliance with the Drug Services Handbook.

9. The Drug Services Handbook requires a medication be medically necessary.

10. The above Handbook identifies a PDL of safe and cost effective medications. Medications appearing on the PDL must first be prescribed. If unsuccessful, medications not on the PDL could then be considered.

11. On February 4, 2015[1] Molina issued a notice denying the requested medication. The notice stated, in part:

> The reason for decision was based on the Food and Drug Administrative (FDA) Guidelines Criteria for the use of Lidocaine 5% ADH Patch, which states that this medication is indicated for the treatment of Post herpetic Neuralgia. Your chart notes from Dr. [redacted] indicate that you are being prescribed Lidocaine 5% ADH Patch for knee/leg pain; therefore, you do not meet the indicated treatment for this medication.

12. Post herpetic neuralgia is skin and nerve pain associated with shingles.

13. Petitioner is not diagnosed with shingles.

14. FDA Guidelines also call for lidocaine patches for the treatment of diabetic neuropathy.

15. Petitioner is not diagnosed with diabetic neuropathy.

16. On February 24, 2015 the Office of Appeal Hearings timely received petitioner's request for a fair hearing.

17. At the time of Molina's denial notice, lidocaine patches were not on respondent's PDL. On March 2015, however, the PDL was updated to include lidocaine 5% patches. A prior authorization is not needed under the following conditions:

- The patches are needed to treat herpes zoster or post herpetic neuralgia
- Diagnosis of neuralgia (code 729.2); diabetic neuropathy; diabetic peripheral autonomic neuropathy; and diabetic polyneuropathy.

18. Petitioner argues the lidocaine 5% patch was used during hospitalization and thereafter provided by Magellan Complete Care. As some pain medications make him ill, the patch was an effective alternative. Additionally, the cost to independently fill the

[1] A revised notice was issued on April 8, 2015. The revision changed wording from knee/leg pain to foot/ankle pain.

prescription is approximately $200.00 per month. Petitioner cannot afford to independently purchase the lidocaine patches.

19. Respondent asserts the medical information provided by the treating physician does not warrant lidocaine patches. The encounter summary of January 23, 2015 does not indicate post herpetic neuralgia or any type of diabetic related neuropathy.

CONCLUSIONS OF LAW

20. By agreement between the Agency for Health Care Administration and the Department of Children and Families, AHCA has conveyed jurisdiction to the Office of Appeal Hearings to conduct this hearing pursuant to § 120.80, Fla. Stat.

21. This is a final order pursuant to § 120.569 and § 120.57, Fla. Stat.

22. This hearing was held as a *de novo* proceeding pursuant to Fla. Admin. Code R. 65-2.056.

23. The burden of proof is assigned to the petitioner. The standard of proof in an administrative hearing is by a preponderance of the evidence. (See Fla. Admin. Code R. 65-2060(1).) The preponderance of the evidence standard requires proof by "the greater weight of the evidence," (Black's Law Dictionary at 1201, 7th Ed.).

24. The Florida Medicaid program is authorized by Fla. Stat. ch 409 and Fla. Admin. Code R. 59G. The Medicaid program is administered by the respondent.

25. Section 409.912, Fla. Stat. states, in relevant parts:

> Cost-effective purchasing of health care. — The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care ...
>
> (3) The agency may contract with health maintenance organizations certified pursuant to part I of chapter 641 for the provision of services to recipients. This subsection expires October 1, 2014.

26. The Florida Medicaid Provider Handbook (Provider Handbook) is incorporated by reference in the Medicaid Services Rules found in Fla. Admin. Code Chapter 59G-4. In accordance with the above Statute, the Handbook states on page 1-27:

> Medicaid contracts with Health Maintenance Organizations (HMOs) to provide prepaid, comprehensive, cost-effective medical services to enrolled Medicaid recipients.
>
> Medicaid pays each HMO a monthly capitation fee for managing and providing care to each enrolled recipient. In accordance with certain contractual agreements with Medicaid, the HMO provides a specified, comprehensive package of medical services for this monthly Medicaid fee.

27. In this instant appeal, Molina is the health maintenance organization which provides petitioner's Medicaid services.

28. Page 1-28 of the Provider Handbook lists HMO covered services. The service list includes prescribed drug services.

29. Page 1-30 of the Provider Handbook states: "An HMO's services cannot be more restrictive than those provided under Medicaid fee-for-service."

30. The Drug Services Handbook has been promulgated into rule by reference in Fla. Admin. Code R. 59G-4.250. Page 2-2 states, in part: "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 specialists approved by the Agency."

31. The definition of "medically necessary" is found in the 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.

32. The Drug Handbook addresses the PDL on page 2.4 and states, in 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 none-PDL product.
...

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

33. It is noted the lidocaine patches were not on the PDL when denied by Molina on February 4, 2015. Since that time, the patches appear on the PDL. The Findings of Fact establish the patches do not require prior authorization when the recipient is diagnosed with herpes zoster; post herpetic neuralgia; or specified diabetic neuropathies.

34. No evidence was presented the petitioner has been diagnosed with any of the conditions specified by the above referenced guideline.

35. No other guidelines were provided stating lidocaine 5% patches are appropriate treatment for those diagnoses identified by petitioner's physician[2].

36. No medical documentation was presented that other pain protocols have been attempted and failed.

37. Petitioner has not established the following conditions of medical necessity have been satisfied:

> 2. Be individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the patent's needs;
>
> 3. Be consistent with generally accepted professional medical standards as defined by the Medicaid program and not be experimental or investigational;

38. Petitioner has not established, by the greater weight of the evidence, that respondent's denial of the lidocaine 5% patches was improper.

DECISION

Based upon the foregoing Findings of Fact and Conclusions of Law, petitioner's appeal is denied.

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

[2] As found on the encounter summary dated January 23, 2015.

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 12th day of May, 2015,

in Tallahassee, Florida.

Frank Houston
Hearing Officer
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