

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

LAWRENCE ABELE,

Petitioner,

vs.

Case No. 20-0056

DEPARTMENT OF MANAGEMENT SERVICES,
DIVISION OF STATE GROUP INSURANCE,

Respondent.

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RECOMMENDED ORDER

On March 17, 2020, Administrative Law Judge Yolonda Y. Green, of the Division of Administrative Hearings (“DOAH”), conducted a hearing pursuant to section 120.57(1), Florida Statutes (2019), in Tallahassee, Florida.

APPEARANCES¹

For Petitioner: Lawrence Abele, pro se
841 Maderia Circle
Tallahassee, Florida 32312

For Respondent: Erica D. Moore, Esquire
Gayla Grant, Esquire
Office of the General Counsel
Department of Management Services
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STATEMENT OF THE ISSUE

The issue to be determined in this proceeding is whether Petitioner is entitled to a refund of the costs paid for prescriptions for compound Midrin.

PRELIMINARY STATEMENT

Petitioner requested payment for certain medical expenses, which was denied on March 20, 2019. By letter dated April 22, 2019, Respondent notified Petitioner that his Level I clinical appeal was denied. On May 8, 2019, dissatisfied with the outcome of the Level I appeal, Petitioner filed a request for a Level II appeal with Respondent. The Level II appeal was also denied. Petitioner then requested an informal hearing.

On December 6, 2019, an informal hearing was convened, during which the presiding hearing officer determined that there was a disputed issue of material fact presented by the case. The hearing officer entered an Order Transferring Matter to the Division of Administrative Hearings (DOAH). On January 7, 2020, Respondent referred the dispute to DOAH, which scheduled and conducted the formal hearing.

At the hearing, Petitioner testified on his own behalf. Respondent presented the testimony of four witnesses: Dr. Anthony Arnett (senior medical director in medical affairs for Caremark); Dearline Thomas-Brown, MPH, BSN, RN (legal nurse coordinator for DMS); Adam Korn (senior director of client operations); and Dr. John Ness (Petitioner's primary care physician). Respondent also offered Exhibits 1 through 5, 7, and 8, which were admitted into evidence.

¹ The attorney for CVS Caremark (Caremark), Jacob Koffsky, Esquire, of Foley & Lardner LLP, represented witnesses who are current employees of Caremark during the proceeding. However, Caremark was not a named party in this proceeding.

The one-volume Transcript of the hearing was filed on April 14, 2020. Both parties timely filed post-hearing submittals, which have been considered in the preparation of this Recommended Order.

Unless specifically stated otherwise herein, all references to Florida Statutes will be to the 2018 codification.

FINDINGS OF FACT

1. The Division of State Group Insurance (Division) is the executive agency within the Department of Management Services (Department) that is responsible for the administration of the State Group Insurance Program (Program).

2. Petitioner is retired and receives medical benefits through the State Employees' HMO Standard Medical Plan (the Plan), which is administered by Capital Health Plan (CHP).

3. The State Employees' Prescription Drug Program is administered by CVS Caremark. Respondent is the state agency responsible for resolving appeals of medical claims denied by Caremark.

Background

4. Mr. Abele was employed with the State of Florida until he retired. He was covered by the Plan and his coverage has remained since his retirement.

5. For the past three years, Mr. Abele has filled a prescription for generic Midrin to treat migraine headaches. The medication was prescribed by his primary care physician, John Ness, M.D.

6. The evidence offered at hearing includes a total of 18 claims² for prescriptions for compound Midrin that Mr. Abele submitted to Caremark for reimbursement. Mr. Abele submitted claims for prescriptions filled in 2018 dated: July 12 and 25, 2018; August 2, 2018; September 7, 2018; October 5 and 22, 2018; November 6 and 26, 2018; December 12, 2018. Mr. Abele also submitted claims for prescriptions filled in 2019 dated: January 9 and 30,

2019; February 12, 2019; March 6, 18, and 29, 2019; April 10 and 25, 2019; and May 10, 2019. Each of the 18 claims was for reimbursement of \$105 for a total of \$1,890.

Relevant Definitions

7. The Plan Booklet and Benefit Document (“Plan”) includes definitions, relevant in part here, as follows:

"Covered Services and Supplies" means those health care services and supplies, including pharmaceuticals as described in Section VIII, for which reimbursement is covered under this Plan.

"Exclusions" is defined as any provision of the Plan whereby coverage for a specific hazard or condition is entirely eliminated.

“Medically Necessary” is defined as any appropriate medical treatment ... as provided by a physician ... which is necessary for the diagnosis, care and/or treatment of a Health Plan Member’s illness or injury, and which is:

- Consistent with the symptom, diagnosis, and treatment of the Health Member’s condition;
- The most appropriate level of supply and/or service for the diagnosis and treatment of the Health Plan Member’s condition;
- In accordance with standards of acceptable community practice;
- Not primarily intended for the personal comfort or convenience of the Health Plan Member, the Health Plan Member’s family, the physician or other health care providers;
- Approved by the appropriate medical body or health care specialty involved as effective,

² The claims at issue are those claims submitted by Mr. Abele in support of his request for reimbursement.

appropriate and essential for the care and treatment of the Health Plan Member's condition; and

- Not Experimental or investigational.

Medical Necessity

8. Dr. Ness, a family practice physician with 30 years of experience, prescribed generic Midrin for Mr. Abele to treat migraine headaches. Dr. Ness prescribed generic Midrin to treat Mr. Abele based on his assessment that other medications were contraindicated for Mr. Abele due to Mr. Abele's risk for cardiovascular adverse effects if he uses other medications. Dr. Ness credibly testified that Midrin is medically necessary to treat Mr. Abele's migraine headaches.

9. Anthony Arnett, M.D., the physician for Caremark responsible for reviewing claims for coverage, determined that Midrin was not medically necessary to treat Mr. Abele's migraine headaches. However, Dr. Arnett conceded that his decision was based on his general determination that there are other options available for migraine headaches.

10. The undersigned finds Dr. Ness' testimony more persuasive concerning the determination that Midrin was medically necessary to treat Mr. Abele for migraines.

Midrin History

11. At the time Dr. Ness prescribed generic Midrin to Mr. Abele, it was an FDA-approved drug. In fact, Midrin was approved for use in 1948 based on safety and effectiveness. However, in 2017, the United States Food and Drug Administration (the "FDA") determined that Midrin was no longer safe and effective.

12. On October 12, 2017, the FDA notified manufacturers of prescription drugs containing isometheptene mucate that they should immediately cease distribution of the product. On June 13, 2018, the FDA issued a subsequent notice listing the drugs that were no longer approved by the FDA and that

manufacturing companies were required to stop producing. The drug combination for Mr. Abele's prescription for compound Midrin (acetaminophen, dichloralphenazone, and isometheptene mucate) is on the FDA non-approved list.

Midrin Prescription/Coverage Denial

13. In January 2018, Mr. Abele presented his prescription for generic Midrin to his local CVS Pharmacy to be filled but the prescription was refused. Mr. Abele indicated that the pharmacist told him that the manufacturer had stopped producing the drug and suggested that he could have the drug compounded.

14. Since generic Midrin was no longer available, Dr. Ness issued a prescription for the compound Midrin, in capsule form, with a 10-day supply for each prescription. The medication name was listed as "Midrin (ALTERNATE) 325MG/100MG/65MG Capsule," and the ingredients were listed as acetaminophen, dichloralphenazone, isometheptene mucate, and microcrystalline cellulose³. Mr. Abele filled the prescriptions at a local in-network compounding pharmacy.

15. On January 14, 2018, Mr. Abele contacted Caremark about his compound Midrin prescription and Mr. Abele was told that he would need to submit a claim to determine whether the compound drug ingredients would be covered. There is no evidence that the Caremark representative made any false or misleading representation that Mr. Abele's compound prescription would be approved.

16. On December 14, 2018, Mr. Abele submitted claims to Caremark for reimbursement for compound Midrin. On December 17, 2018, Caremark notified Mr. Abele by letter that the claims he submitted were not allowed. The reason provided for disallowance was because the drug was not on the plan's formulary. The letter also notified Mr. Abele that his request for exception did not include the information necessary to approve the request.

17. On February 1, 2019, Dr. Ness, on behalf of Mr. Abele, submitted a non-covered drug formulary exception request seeking approval for compound Midrin. He requested the drug in capsule form for the treatment of Mr. Abele's migraines. However, the request form did not include a copy of the prescription for the compound formula for Midrin. The form also did not describe the drug as the compound alternative. Dr. Ness testified that it is a common medical practice to use "cap" to refer to the capsule form, even for the compound formula.

18. The Caremark appeals department faxed a response to Dr. Ness as follows: "In researching your fax request, the member's prescription benefit coverage indicates a [p]rior [a]uthorization is NOT required. For additional questions regarding the medication's coverage under the member's plan, please contact Customer Service using the number on the back of the member's prescription benefit card."

19. Dr. Anthony Arnett testified that he interpreted the exception request as being for Midrin capsules, rather than the compound form. Based on that interpretation, the response to the exception request was that prior authorization was not necessary. The undersigned finds that even if prior authorization was not required for the prescription, it does not amount to an approval for coverage of the claims.

Appeal of Coverage Denial

20. On February 5, 2019, Mr. Abele appealed the denial of reimbursement for compound Midrin. On February 13, 2019, Caremark responded to Mr. Abele instructing him to submit additional information for his claims to be processed. On February 18, 2019, he submitted the requested information and materials.

21. On March 30, 2019, Caremark notified Mr. Abele by letter that his drug coverage request was denied. The basis for the denial was that the

³ Microcrystalline cellulose may be used as a bulking agent in pharmaceutical products.

prescription was for a compound drug containing, as relevant here, bulk powder.

22. Mr. Abele then submitted a Level I appeal, also referred to as a clinical appeal⁴, on April 18, 2019. Dr. Arnett reviewed Mr. Abele's claims for the Level I appeal. While Dr. Arnett acknowledged that compounding could be approved if no other drug is available for treatment of migraines, he concluded that Mr. Abele's exception request could not be approved because the compound formula included bulk powder.

23. Caremark denied Mr. Abele's Level I appeal and notified Mr. Abele by letter of their decision on April 22, 2019. In the letter, Caremark stated that "petitioner's appeal for Dichloralphenazone Powder Compound has been determined as not medically necessary; and, 'the plan criteria does not allow coverage of dichloralphenazone Powder Compound' if the compound contained 'bulk powder' as an ingredient."

24. On May 8, 2019, dissatisfied with the outcome of the Level I appeal, Mr. Abele requested a Level II appeal. The Department denied the Level II appeal on the basis that the compound Midrin "did not meet the medical necessity criteria and non-FDA approved compounds are excluded from the plan."

Limitations and Exclusions

25. The Department's concurrence of Caremark's decision that coverage for the compound Midrin prescription should be denied was based on the Plan's general Limitations and Exclusions section, which applies to the Prescription Drug Program. The Prescription Drug Program also outlines specific exclusions related to medications.

26. The Prescription Drug Program, described in Part VIII, provides that covered drugs shall include, but are not limited to, any drug, medicine, medication, or communication that is consumed, administered, or provided at

⁴ Level I appeals are handled by Caremark by a specific group that focuses on prescriptions appeals.

the place where the prescription is given at the medical provider's office or healthcare facility.

27. The Plan's limitations and exclusions section provides, "the following services and supplies are excluded from coverage under this Plan unless a specific exception is noted. Exceptions may be subject to certain coverage Limitations." Under the Plan, the exclusions include "any non-prescription medicine, remedy, biological product, pharmaceutical or chemical compound, vitamins, mineral supplements, fluoride products, health foods, or blood pressure kits, except as specifically provided for in the covered benefits section under prescription drugs."

28. The Additional Exclusions section provides that bulk powders, bulk chemicals, and proprietary bases used in compound medications and over-the-counter ("OTC") products used in compound medications are excluded from coverage. Further, the plan excludes services or supplies not medically necessary as determined by the Plan and/or the Prescription Drug Program clinical staff and the state.

29. The Prescription Drug Program provides that the Prescription Drug Program does not cover non-federal legend or OTC products, and bulk powders, bulk chemicals, and proprietary bases used in compounded medications.

CONCLUSIONS OF LAW

30. DOAH has jurisdiction of the subject matter of and the parties to this proceeding. §§ 120.569 and 120.57(1), Fla. Stat.

31. Respondent is the state agency with the duty to oversee the administration of the Program. § 110.123, Fla. Stat.

32. The Plan is a health insurance benefit enacted by the Florida Legislature and offered by Respondent. § 110.123, Fla. Stat.

33. Section 110.123(5), Florida Statutes, assigns responsibility for final decisions on matters of the existence of coverage or covered benefits under the Program to Respondent.

34. In an administrative proceeding such as here, the party asserting the affirmative of an issue has the burden to prove by a preponderance of the evidence that it is entitled to the relief sought. *Alexander v. Dep't of Mgmt. Servs.*, Case No. 13-2095, RO at 20 (Fla. DOAH Aug. 16, 2013)(citing *Young v. Dep't of Cmty. Aff.*, 625 So. 2d 831, 833-34 (Fla. 1993)); *Dep't of Transp. v. J.W.C. Co.*, 396 So. 2d 778, 788 (Fla. 1st DCA 1981); *Balino v. Dep't of HRS*, 348 So. 2d 349, 350 (Fla. 1st DCA 1977). As the party asserting the right to payment of his claims under the Plan, the Petitioner had the initial burden of demonstrating by a preponderance of the evidence that his claim is qualified for coverage. Assuming Petitioner meets this requirement, the burden then shifts to Respondent to establish that the claim is excluded from coverage under the terms of the policy. *See Young v. Dep't of Cmty. Aff.*, 625 So. 2d 831 (Fla. 1993); *Herrera v. C.A. Seguros Catatumbo*, 844 So. 2d 664, 668 (Fla. 3d DCA 2003); *State Comprehensive Health Ass'n v. Carmichael*, 706 So. 2d 319, 320 (Fla. 4th DCA 1997).

35. In this case, Petitioner has established that his claims were medically necessary to treat his migraines. However, he has not established that the claim is qualified for coverage. Although the Petitioner testified that Caremark previously paid the claims for Petitioner's generic Midrin prescription, the evidence established that the compound Midrin was excluded from coverage under the prescription plan.

36. Petitioner contends that even if the prescription for compound Midrin was excluded from coverage, he is entitled to reimbursement for the claims in question because he detrimentally relied upon representations from Caremark when he paid for compound Midrin medication. Petitioner believed he would be reimbursed for the claims for the prescriptions based on the

statements and documents from Caremark. Petitioner is relying upon the doctrine of equitable estoppel to support his claim.

37. In order to demonstrate estoppel, [Petitioner] must show that:

(1) a [Petitioner] represented a material fact contrary to its later-asserted position; (2) the [Petitioner] relied on the Division's earlier representation; and (3) the [Petitioner] changed positions to [his] detriment due to the agency's representation and [his] reliance thereon. Unlike the elements to demonstrate entitlement to coverage under the Plan, the elements of estoppel must be proved by clear and convincing evidence.

Hoffman v. Dep't of Mgmt. Servs., Div. of Ret., 964 So. 2d 163 (Fla. 1st DCA 2007).

38. Clear and convincing evidence "requires more proof than a 'preponderance of the evidence' but less than 'beyond and to the exclusion of a reasonable doubt.'" *In re Graziano*, 696 So. 2d 744, 753 (Fla. 1997).

39. Here, Petitioner relied upon statements included in the documents and phone calls with Caremark and asserted that Respondent made a false or misleading statement. He relied upon Caremark's response to the request for exception indicating prior authorization is not required. That statement alone is not sufficient to prove by clear and convincing evidence Respondent made a misleading statement which could reasonably lead Petitioner to ascertain that his claims would be approved. Second, he asserts that Caremark requested additional receipts and information when each claim was submitted. Again, Caremark did not make any representation that the claim would be approved. To the contrary, Caremark's request for additional information was merely an attempt to obtain sufficient information and receipts necessary to make a final determination concerning whether coverage would be approved. While Caremark did not specifically state the claim was still pending until all information was received, there is no clear

and convincing evidence that Respondent made a false or misleading statement.

40. Based on the foregoing, Petitioner has not proved that he is entitled to reimbursement for the claims he submitted because compound Midrin was excluded from coverage and he has not met the requirements for the doctrine of equitable estoppel to apply in this matter.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Division of State Group Insurance, Department of Management Services, enter a final order denying Lawrence Abele's request for reimbursement for the claims submitted for his compound Midrin prescription.

DONE AND ENTERED this 14th day of May, 2020, in Tallahassee, Leon County, Florida.



YOLONDA Y. GREEN
Administrative Law Judge
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Filed with the Clerk of the
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this 14th day of May, 2020.

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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this Recommended Order. Any exceptions to this Recommended Order should be filed with the agency that will issue the Final Order in this case.