# STATE OF FLORIDA
# DIVISION OF ADMINISTRATIVE HEARINGS

AMY BACO-TAYLOR,

Petitioner,

vs. Case No. 21-2236

DEPARTMENT OF MANAGEMENT SERVICES,
DIVISION OF STATE GROUP INSURANCE,

Respondent.
_____/

## RECOMMENDED ORDER

Pursuant to notice, a formal administrative hearing was conducted before Administrative Law Judge ("ALJ") Yolonda Y. Green of the Division of Administrative Hearings ("DOAH") on October 25 and 27, 2021, by Zoom Conference with the ALJ located in Tallahassee, Florida.

## APPEARANCES

For Petitioner: Amy Baco-Taylor, pro se
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Tallahassee, Florida 32312

For Respondent: Erica D. Moore, Esquire
Department of Management Services
Division of State Group Insurance
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## STATEMENT OF THE ISSUE

Whether Petitioner's request for coverage of intravenous immunoglobulin (Gammagard Liquid) ("IVIG") is a covered medication pursuant to the State Employees' Plan ("Plan"), administered by Capital Health Plan ("CHP") through CVS Caremark ("Caremark").

## PRELIMINARY STATEMENT

Petitioner is a member of the Plan as an employee of the State of Florida. Petitioner was diagnosed with Sjogren's syndrome, anti-phospholipid syndrome, small fiber neuropathy, and Postural Orthostatic Tachycardia Syndrome ("POTS"). Her provider submitted a request for IVIG for treatment of her condition. On June 3, 2021, Respondent issued a Level II Appeal Determination letter, denying coverage for IVIG because "your medical records indicate your condition does not meet the medically necessary coverage criteria for IVIG under your plan. Additionally, your provider off-label use request is considered experimental/investigational which is a specific plan exclusion." On July 1, 2021, Petitioner appealed and filed a petition for administrative hearing.

On October 25, 2021, the final hearing was held. Petitioner testified on her own behalf and presented the testimony of Victor McMillan, M.D., Petitioner's treating physician for autoimmune disorders; Gadi Silberman, M.D., Petitioner's treating physician for dysautonomia and POTS; Christopher Taylor, Petitioner's husband; and E. Brendan Roark, Ph.D., Petitioner's colleague. Respondent presented the testimony of Edward "Paul" Amundson, M.D., offered as an expert in claims management and family medicine; and Dearline Thomas-Brown, MPH, BSN, RN, legal nurse coordinator for Respondent. Petitioner's Exhibits 1 through 17 were admitted into evidence. Respondent's Exhibits 1 through 14 were admitted into evidence.

Respondent's Motion for Confidential Court Filing of Proposed Recommended Order, filed post-hearing on December 9, 2021, is granted. As a result of the undersigned's ruling, both Petitioner's and Respondent's Proposed Recommended Orders ("PRO") shall remain confidential.

The three-volume Transcript of the final hearing was filed with DOAH on November 30, 2021. The parties timely filed their PROs and both submittals have been considered in preparation of this Recommended Order.

All references to the Florida Statutes are to the 2020 version, unless otherwise specified.

## FINDINGS OF FACT

1. Respondent is the state agency charged with administering the state employee health insurance program pursuant to section 110.123, Florida Statutes.

2. At all times material hereto, Petitioner was a member of the Plan. CHP is a third-party administrator for the Plan at issue in this case. As the third-party administrator, CHP provides claims processing, utilization, and benefit management services. The applicable benefit document is the State Employees' HMO Plan, Group Health Insurance Plan Booklet and Benefits Document ("Plan Document"), effective January 1, 2019. The Plan Document includes a Prescription Drug Plan ("PDP"), which states certain medications are available only through Caremark. Caremark is the Pharmacy Benefit Manager ("PBM") for the PDP at issue in this cause.

3. As the PBM, CVS provides claims processing, utilization, and benefit management services for prescription drugs. Injectable drugs, such as IVIG, are also subject to CVS's Specialty Guideline Management policy, Reference # 2041-A.

4. Petitioner is a 47-year-old woman who was diagnosed with Sjogren's syndrome, anti-phospholipid syndrome, small fiber neuropathy, and POTS. The Petitioner testified that her medical condition has significantly reduced her quality of life, her ability to complete activities of daily living, her interactions with her children, and the quality of life and health of her spouse. Petitioner also explained the effects the medical conditions have had

on her career as an oceanographer. Specifically, she has been unable to participate in field research at sea, to travel, or to stand for reasonable periods of time.

5. Petitioner, through her treating rheumatologist, Dr. McMillan, submitted a request for coverage of IVIG to Caremark.

6. Authorization for a specialty drug can be obtained based on the application of currently acceptable medical guidelines. IVIG is one of the specialty drugs for which satisfaction of the medical review criteria is required.

7. Thus, IVIG is only available through Caremark, as a specialty drug, subject to review and approval under Caremark's Specialty Guideline Management Program.

8. On February 9, 2021, CVS denied the pre-service request for coverage on the basis that coverage for the drug is not allowed unless the patient had one of the listed conditions. Coverage for small fiber neuropathy was not listed as a basis for coverage.

9. On March 8, 2021, Petitioner submitted a request for a Level I appeal to CVS. The appeal was reviewed by Dr. Stephen Selkirk, M.D., a consultant specializing in neurology, who is under contract with CVS for review of requests. He filed a report dated March 9, 2021.

10. On March 10, 2021, CVS denied the request for Level I appeal on the basis that due to a lack of high-quality clinical trials, the standard of care guidelines do not support the use of IVIG for small fiber neuropathy. Therefore, the appeal was denied because it was deemed experimental/investigational and, as a result, not medically necessary for the treatment of Petitioner's conditions.

11. On May 3, 2021, Petitioner submitted a request for a Level II appeal to Respondent. The Level II appeal was reviewed by Dearline Thomas-Brown, a registered nurse and Level II appeal coordinator for Respondent.

12. On June 3, 2021, Respondent denied Petitioner's Level II appeal on the basis that the treatment is not medically necessary for treatment of the member's condition and is experimental/investigational.

13. Prior to Petitioner filing the Petition for Formal Hearing, her request was submitted for an external review which was reviewed by an Independent Review Officer ("IRO"). The review was completed by a board-certified internal medicine doctor with certification in rheumatology, and a report was generated on September 8, 2021. The "List of Records Reviewed" included Petitioner's medical records, including laboratory results and clinical notes, denial letter, patient appeal letter, and policy criteria guidelines. The IRO upheld the denial and noted that medical necessity has not been established. The IRO stated that "[IVIG] has not been approved by the appropriate medical body or board for the illness of small fiber neuropathy associated with Sjogren's syndrome. Therefore, the requested health service is not medically necessary … ."

14. The Plan Document, Section I, entitled Introduction pertaining to medical claims, provides in relevant part:

> The Plan is not intended to and does not cover or provide any Medical Services or benefits that are not Medically Necessary for the diagnosis and treatment of the Health Plan Member. Capital Health Plan determines whether the services are Medically Necessary on the basis of terms, conditions, and criteria established by the Plan as interpreted by the state, and as set forth in medical guidelines.

15. To be a covered drug, the drug must be "medically necessary," not "experimental or investigational," and it must not be specifically excluded by the Plan. The Plan provides that:

> Pursuant to the Plan, "Medically Necessary" is defined as follows:

> The use of any appropriate medical treatment, service, equipment and/or supply as provided by a Hospital, skilled nursing facility, physician or other provider 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 Plan 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 medical 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, appropriate and essential for the care and treatment of the Health Plan Member's condition; and
>
> • Not experimental or investigational.

16. The medical treatment must meet all of the appropriate criteria to be considered "medically necessary." Given the above definition, if a service is experimental or investigational, then it cannot be medically necessary.

17. Section VI, Limitations and Exclusions of the Plan Document, specifically excludes services that are "experimental/investigational or not medically necessary treatment."

18. Pursuant to the Plan "Experimental and/or Investigational" is defined as follows:

> For the purposes of the Plan a medication, treatment, device, surgery or procedure may

> initially be determined by CHP to be experimental and/or investigational if *any* of the following applies:
>
> • The FDA has not granted the approval for general use; or
>
> • There are insufficient outcomes data available from controlled clinical trials published in peer-reviewed literature to substantiate its effectiveness for the disease or injury involved; or
>
> • There is no consensus among practicing physicians that the medication, treatment, therapy, procedure or device is safe or effective for the treatment in question or such medication, treatment, therapy, procedure or device is not the standard treatment, therapy procedure or device utilized by practicing physicians in treating other patients with the same or similar condition; or
>
> • Such medication, treatment procedure, or device is the subject of an ongoing Phase I or Phase II clinical investigation, or Experimental or research arm of a Phase III clinical investigation, or under study to determine: maximum tolerated dosage(s), toxicity, safety, efficacy, or efficacy as comparted with the standard for treatment or diagnosis of the condition in question.

19. If any one or more of the criteria set forth in the definition are met, then the treatment is "experimental and/or investigational" and is not covered under the Plan.

20. To reach their respective determination for denial of Petitioner's request for coverage for IVIG, all reviewers for the levels of appeal utilized CVS's guidelines for use of IVIG for treatment. These specialty coverage guidelines provide CHP's "exclusion criteria" which indicated IVIG is not covered and is considered experimental and investigational and not medically necessary.

21. The specialty coverage guidelines are intended to be used in conjunction with the Plan to determine whether medication is medically necessary and a covered benefit. IVIG may be used to treat collagen vascular disease, which includes Sjogren's syndrome.

22. Dr. McMillan wrote a letter on Petitioner's behalf requesting use of the medication and appealing denial of the medication. Dr. McMillan also testified at the hearing in support of Petitioner's efforts to obtain coverage through CHP for IVIG.

23. Dr. McMillan is board-certified in internal medicine with a subspecialty in rheumatology. He has also written several publications regarding Sjogren's syndrome. Dr. McMillan's testimony is accepted as Petitioner's treating physician and expert in the area of internal medicine and rheumatology.

24. Dr. McMillan determined IVIG was appropriate for treatment of Petitioner's condition and noted that it has been shown to be effective for severe or treatment-refractory in small published reports. He pointed to literature (Farhard) that focused on a small, uncontrolled study which resulted in successful treatment with trial of IVIG in patients with Sjogren's syndrome. Of note, is that the study itself acknowledged that it was a small study, and there were few studies on the use of IVIG for Sjogren's syndrome.

25. Petitioner's physician, Gadi Silberman, M.D., also sought to treat her condition with IVIG. Dr. Silberman testified that the treatments that have been tried so far for Petitioner are not adequate to treat her conditions. Dr. Silberman also testified that a patient's quality of life and ability to perform activities of daily living are important considerations in determining whether a medication is "medically necessary."

26. Dr. Amundson, a board-certified physician in Family Medicine with training in internal medicine, testified as Respondent's expert. He has no training in neuropsychology or cardiology. In addition, unlike Dr. McMillan, he does not have a specialty in rheumatology. The parties stipulated to

Dr. Admundson as an expert. However, his testimony, when weighed against the testimony of Dr. McMillan, a current practicing specialist in the field of rheumatology, is given lesser weight.

27. As noted herein, the criteria to determine whether a treatment or procedure is "medically necessary" under the Plan includes six criteria. Dr. Amundson testified, in relying upon the report from the IRO, that IVIG does not meet criteria five and six.

28. IVIG does not meet the fifth criterion of the definition of "medically necessary," as IVIG has not been approved by the appropriate medical body or healthcare specialty involved as effective, appropriate, and essential for the care and treatment of small fiber neuropathy. IVIG is not essential for the treatment of Petitioner's condition.

29. In addition, use of IVIG does not meet the sixth criterion of the definition of "medically necessary," as it meets the definition of "experimental and/or investigational."

30. If any of the criteria of the definition of "experimental and/or investigational" are met, then IVIG would be considered "experimental and/or investigational." As set forth in paragraph 18 herein, there are five criteria for determining whether a treatment or procedure is "experimental and/or investigational."

31. Here, criterion two of the definition of "experimental and/or investigational" is met, which leads to the ultimate conclusion that IVIG is not medically necessary in this case. Sufficient outcome data are not available from controlled clinical trials published in peer-reviewed literature to substantiate IVIG's safety and effectiveness for treatment of small fiber neuropathy. Currently randomized trials have been published in peer-reviewed medical literature. However, there are only small controlled studies pertaining to IVIG medication treatment for small fiber neuropathy. Dr. Amundson testified that there is a lack of peer-reviewed, published, randomized studies regarding IVIG. Thus, the treatment meets criterion two.

Nurse Thomas-Brown testified that a treatment considered experimental or investigational is, automatically, not medically necessary.

32. Both parties relied upon information from medical journals and publications in support of their respective positions. In addition, Respondent relied upon the IRO report and its statements. The individual who prepared the report did not testify at the hearing. Thus, the report and any statements therein are considered hearsay. Generally, hearsay statements, without corroboration by a person with knowledge of the area at issue, could not be relied upon to make findings of fact.

33. Here, Dr. Amundson did not prepare the IRO report. However, he testified about the findings based on his knowledge of the subject matter.

34. Overall, Petitioner established that use of IVIG was medically necessary from a clinical standpoint. The use of IVIG for small fiber neuropathy associated with Sjogren's syndrome is not approved by the Federal Drug Administration (FDA). The use of a drug for a purpose other than the uses approved by the FDA is referred to as an "off-label" use. The off-label use of IVIG for Sjogren's syndrome as being effective from a medical standpoint under the Plan has not been demonstrated in this case.

35. There was conflict in the evidence as to whether use of IVIG for Petitioner's condition is medically necessary from a clinical standpoint or medically necessary under the Plan. The undersigned finds as follows regarding that conflict. Based on the applicable criteria under the Plan, the evidence presented at hearing, including medical records produced by Petitioner and supporting literature, fails to demonstrate that Petitioner had a medical condition that warranted coverage of treatment with IVIG.

36. Petitioner did not establish at this time that IVIG is medically necessary, as defined by the Plan, and did not establish that IVIG is not experimental and/or investigational.

37. There was some testimony offered at the final hearing that use of IVIG may be used for Sjogren's as a collagen vascular disease. However, there was

no evidence in the record to support collagen vascular disease being the stated diagnosis for treatment with IVIG.

## CONCLUSIONS OF LAW

38. DOAH has jurisdiction over the parties to and the subject matter of this proceeding. §§ 120.569 and 120.57, Fla. Stat.

39. Respondent is the state agency charged by the Legislature with oversight of the administration of the state group insurance program. § 110.123(3)(c), Fla. Stat

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

41. In administrative proceedings, the party asserting the affirmative of an issue is required to prove that he or she is entitled to the relief sought. *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). The burden of proof that applies is a preponderance of the evidence. § 120.57(1)(j), Fla. Stat. In this proceeding, Petitioner bears the burden of proving by a preponderance of the evidence that IVIG is a prescription benefit covered under the Plan. If Petitioner meets this requirement, then the burden shifts to Respondent to prove that the claims were not covered due to the application of a policy exclusion. *Herrera v. C.A. Seguros Catatumbo*, 844 So. 2d 664 (Fla. 3d DCA 2003); *State Comp. Health Ass'n v. Carmichael*, 706 So. 2d 319, 320 (Fla. 4th DCA 1997).

42. In this case, one criterion in the definition of "medically necessary" is that the treatment at issue cannot be "experimental and/or investigational." Therefore, in proving that the treatment was medically necessary, Petitioner also had to prove that the treatment was not "experimental and/or investigational," as defined in the Plan. Any treatment, including medication that is experimental and/or investigational is excluded by the Plan.

43. Petitioner failed to meet her burden of proving that IVIG was medically necessary. Petitioner failed to present competent substantial evidence that each of the criteria in the definition of "medically necessary" was met. The greater weight of the evidence presented was that criteria five and six were not met.

44. Additionally, a preponderance of the evidence supports a finding that IVIG for treatment of Petitioner's condition is "experimental and/or investigational" as criterion two of that definition was met. Petitioner failed to present sufficient evidence to rebut Respondent's witness testimony and documentary evidence on this issue. The IRO's report, introduced by Respondent as substantiated by Dr. Admundson, also confirms that IVIG for Petitioner's condition is considered investigational and not a standard of care treatment option. Since the treatment is excluded as an "experimental and/or investigational" service, it also fails to meet the definition of medically necessary treatment.

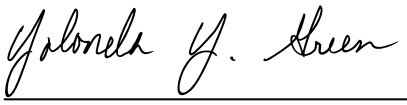
45. There was a dispute regarding the definition of "medically necessary" in this matter. Although Petitioner points out that use of IVIG for small fiber neuropathy is "medically necessary" from a clinical treatment standpoint, again, the issue for determination here is not whether the medication treatment is "medically necessary," from a clinical standpoint, but whether IVIG is "medically necessary" treatment as defined under the Plan. By virtue of the Plan's definition of medical necessity, which controls the benefit determination for its insureds, IVIG for the treatment of small fiber neuropathy is not a covered benefit at this time.

46. Based on the evidence presented at hearing, Petitioner did not establish the criteria for approval of IVIG for Petitioner's condition at this time. Because the treatment is excluded as not "medically necessary" and it is currently deemed "experimental and/or investigational," Petitioner's coverage must be denied.

## RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Department of Management Services, Division of State Group Insurance, enter a final order denying Petitioner's request for coverage for intravenous immunoglobulin (Gammagard Liquid).

DONE AND ENTERED this 2nd day of February, 2022, in Tallahassee, Leon County, Florida.



YOLONDA Y. GREEN
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Filed with the Clerk of the
Division of Administrative Hearings
this 2nd day of February, 2022.

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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.