STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

[redacted]

Petitioner,

vs. Case No. 17-0723

DEPARTMENT OF MANAGEMENT SERVICES, DIVISION OF STATE GROUP INSURANCE,

Respondent.
_____/

RECOMMENDED ORDER

Pursuant to notice, a final hearing was conducted in this case on April 13, 2017, in Tallahassee, Florida, before Administrative Law Judge R. Bruce McKibben of the Division of Administrative Hearings.

APPEARANCES

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STATEMENT OF THE ISSUE

The issue in this case is whether a request by Petitioner, [redacted] for approval of certain medical equipment, specifically the ReWalk™ exoskeleton system ("ReWalk"), should be covered under the State Employees' Preferred Provider Organization ("PPO") insurance plan (the "Plan"). (Petitioner, a medical doctor, will be referred to herein as "[redacted]

PRELIMINARY STATEMENT

By letter dated August 18, 2016, Respondent, Department of Management Services/Division of State Group Insurance (the "Department"), through its administrator, Florida Blue, issued a letter to [redacted] denying her request for Voluntary Pre-Service Coverage Review relating to the ReWalk. [redacted] filed a Level I Appeal to challenge the Department's decision. The Level I Appeal was denied by letter dated September 27, 2016. [redacted] then filed a request for a Level II Appeal; that appeal was denied on December 14, 2016. Petitioner timely filed a request for formal administrative hearing to contest the Level II denial and the case was referred to the Division of Administrative Hearings ("DOAH"). Pursuant to notice, a final hearing was held on the date and time set forth above.

At the final hearing, [redacted] testified on her own behalf and also called one additional witness, Dr. Steven Vanni, accepted as an expert in the treatment of spinal cord injuries

and devices relative to such treatment. [redacted] Exhibits A2 through A7, A9, A11, A13 through A15, A18, A20, B through G, I and J were admitted into evidence. The Department called two witnesses: Dr. Daniel Hudec, accepted as an expert in utilization management as it relates to coverage decisions under the Plan; and Kathy Flippo, nurse consultant for the Division of State Group Insurance ("DSGI"). The Department's Exhibits 1, 2, and 8 through 14 were admitted into evidence.

At the conclusion of the final hearing, the parties advised that a transcript of the proceeding would not be ordered; proposed recommended orders ("PROs") were therefore due on or before April 24, 2017. Seven days after the final hearing, Petitioner filed a notice that a transcript would be ordered after all. The parties were allowed 10 days from the date the transcript was filed at DOAH to file PROs. The Transcript was filed on May 9, 2017; PROs were due May 19, 2017. Each party timely submitted a PRO and each was duly considered in the preparation of this Recommended Order.

FINDINGS OF FACT

1. [redacted] is a licensed neuro-ophthalmologist, but is currently unable to work. She is 50 years old and is married with two children: a daughter, age 12; and a son, age 9. She and her family live in [redacted], Florida. [redacted] is enrolled in the Plan through her husband, who is a state

employee. The Plan is a health insurance plan administered by Florida Blue, a BlueCross BlueShield ("BCBS") affiliate. Florida Blue provides administrative services to the Department, including claims processing and medical coverage guidelines.

2. In 2008, [redacted] had a complicated pregnancy and delivery. After she had recovered from those complications, she was diagnosed with breast cancer. A bilateral mastectomy was performed, followed later by radiation treatment. From all appearances, her cancer went into remission and she was able to continue working in her position as a professor for the University of Florida in the Jacksonville medical center. [redacted] transitioned from the University of Florida professorship to the St. Vincent's Health Care System in Jacksonville, where she served in two hospitals as a hospital neurologist. She also set up a neuro-ophthalmology clinic, which was one of only two in the region.

3. In 2012, [redacted] began having symptoms or indications that something was amiss in her body. She experienced a burning sensation around her waist, heaviness in her right leg, and tingling in her left foot. Based upon her knowledge as a physician, she self-diagnosed the symptoms as possible cancer in her spine, inducing a "cancer fear" yet again. Her symptoms were eventually found to be due to radiation-induced changes to

her spinal cord. The very treatment that had cured her cancer had also damaged her spine.

4. The symptoms continued and her health began to rapidly deteriorate, causing her to have to rely on a roller-aide to assist with ambulation. As her condition deteriorated, she had to rely on a walker. Ultimately, she had to utilize a wheelchair to move around, a device to which she is currently confined. As a result of her condition, [redacted] is no longer able to function as a professor or as a physician.

5. [redacted] described her conditions in layman's terms as follows:

> Well, around my belly button all the way around in a band probably to my mid-hips is super-sensitive to anything. Without medication I can't even have clothes on, and just movement, skin-against-skin is extremely, extremely painful. Burning, electrical sensations. Below that, there's more sensory loss; so say if the shower water is running, the temperature begins to drop off from hips on down. It's different one leg than the other; it's not symmetric for me, because I have what's called an incomplete or a partial spinal cord injury.
>
> And then as you go on down to the feet, one of the sensation modalities I've lost the most is position sense. So with my eyes closed, I don't have legs; except for burning and tingling and electrical sensations, I don't know where they are in space.

6. In order to deal with her condition, [redacted] uses two different wheelchairs, one manual and one electric (scooter

type). The electric scooter allows her some relief from pushing herself up and down ramps, saving her shoulders and arms from excessive stress. She must remain in one of her wheelchairs essentially all day, every day. The pressure of constant sitting, the bone on subcutaneous tissue and muscle, affects her circulation and causes pressure sores. There is extensive sacroiliac pain caused by the inability to walk, the motion if which would otherwise realign her joints naturally, reducing pain. All in all, she suffers greatly because of her immobility.

7. Treatment of spinal cord patients is generally limited to treating the vast array of symptoms, e.g., loss of bowel and bladder functions, pressure sores from constant sitting, atrophy of muscles, poor circulation, loss of bone structure, psychological issues, chronic depression, sleep disturbance, and muscle spasticity, to name a few. These issues are dealt with by therapies and medications, at least historically.

8. There are a number of novel medical approaches focused on assisting patients with spinal cord injuries. For example, physician/scientists are using hypothermia in an attempt to reduce the severity of pain. They have injected Schwann cells in an effort to regrow portions of the spinal cord. Stem cells have been used in an effort to grow neurons back in the spinal cord.

9. A device known as an exoskeleton was created some 15 or so years ago to assist persons who suffer from some spinal cord injuries. The device is an external robotic "skeleton" worn by the patient. The exoskeleton compensates for the patient's loss of muscle control by way of a computer-generated triggering device. The device is attached to the patient's torso and lower extremities, allowing them to ambulate in an upright position. ReWalk is a specific brand or model of the exoskeleton. ReWalk was approved by the U.S. Food and Drug Administration ("FDA") for sale and marketing in 2014 through its "de novo classification process," a regulatory pathway for novel, first-of-its-kind medical devices that are generally low-to-moderate risk. The ReWalk is also cleared for sale and is already in use in the European Union, Canada, and Israel.

10. In July 2016, [redacted] primary care physician, Dr. Fuhrmeister, requested preauthorization from Florida Blue for a ReWalk "to enable [redacted] to become ambulatory." He recognized that many of her pains and discomforts could be relieved if she was able to be mobile separate from her wheelchairs. Dr. Fuhrmeister stated that, "In my medical opinion, the ReWalk Exoskeleton System is medically necessary and reasonable for the health and well-being of [redacted] In his review, Dr. Fuhrmeister identified three peer-reviewed clinical studies to support the efficacy of ReWalk. Those

studies, two in the Journal of Spinal Cord Medicine and one in American Journal of Physical Medicine, did not convince the Department that ReWalk should be an approved device under the Plan.

11. The request for approval of the ReWalk was denied by the Department, based on the following:

> Coverage for the Argo ReWalk Motorized Exoskeleton is denied as it meets the definition of experimental or investigational. There is not enough scientific evidence to support the net effect on the health outcomes of people. Medical Coverage Guideline 09-A0000-03 was used in making this decision.

12. Medical Coverage Guideline 09-A0000-03 states in pertinent part:

> [Florida Blue] uses the following five process/decision variables set forth by the Blue Cross and Blue Shield Association for evaluation and assessment of new technologies and applications of existing technologies:
>
> 1. The technology must have final approval from the appropriate government regulatory bodies, for example, the Food and Drug Administration (FDA).
>
> 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
>
> 3. The technology must improve the net health outcome.
>
> 4. The technology must be as beneficial as any established alternatives.

> 5. The improvement must be attainable outside the investigational setting. For Medicare Advantage products, see the Program Exception section of this guideline.
>
> The list below identifies procedures that do not meet the five process/decision variables listed above and are therefore considered experimental or investigational. This listing is not all-inclusive and any procedure or device that is not listed below or is not included in a medical coverage guideline and does not meet the five process/decision variables may be considered experimental or investigational.
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> [There follows a list of over 100 procedures or devices which are specifically excluded from coverage. ReWalk is not on the list.]

13. When Florida Blue denied the requested authorization for a ReWalk, Dr. Fuhrmeister filed a Level I Appeal on [redacted] behalf. In his appeal letter, Dr. Fuhrmeister noted that, "This technology is entering wide-spread use as ReWalk units have been approved by various insurers and payors around the U.S. The Department of Veterans Affairs is making ReWalk available to wounded veterans . . . ." He also reminded the Department that ReWalk "has not been investigational for two years." And, he added, "[T]his technology now meets a common standard of medical practice."

14. Despite Dr. Fuhrmeister's unequivocal support of ReWalk as acceptable medical technology, the Level I appeal was denied on the following basis:

> Per the State Employees' PPO Plan Booklet and Benefits Document page 5-2:
>
> 'Experimental or investigational services and procedures as determined by Florida Blue and the Division of State Group Insurance are non-covered. Additionally, services and procedures not in accordance with generally accepted professional medical standards, including complications resulting from these non-covered services, are also non-covered.' Specifically, coverage for the ReWalk Exoskeleton device is denied as it meets the definition of experimental or investigational. There is not enough clinical evidence in peer-reviewed medical journals that shows that this service improves health outcomes for people. The medical coverage guideline, 09-A000-03, was used in making this decision. Services that are experimental or investigational are not covered under the member's health benefit plan.

15. Upon receipt of the denial letter, [redacted] filed a Level II Appeal. That appeal, filed by her legal counsel, ReedSmith, provided extensive background and history concerning the ReWalk, its development and usage. The appeal letter cited clinical studies which demonstrate the net health outcomes from the use of ReWalk by persons suffering from spinal cord injuries. ReedSmith pointed out again the number of insurance payors which cover the ReWalk, and that ReWalk is supported by multiple national associations and rehabilitation physicians. And, importantly, the appeal letter suggested that Florida Blue may experience short-term and-long term cost savings due to the reduction of the patient's health needs once ReWalk is employed.

16. In the case of [redacted] there is an entire regimen of medications that could be dramatically reduced as her symptoms are alleviated by the ReWalk. For example, she could conceivably eliminate the need for depression medications and therapeutic counseling as her condition improves. She is likely to not need the various laxatives and bowel medications which are currently necessary. It is quite probable her pain level would decrease, resulting in less reliance on pain medications. She would probably not need the physical therapy she now requires. There would be no need for the ointments and treatments relating to pressure sores. All of these items are currently covered under the Plan, but could be alleviated if the ReWalk was employed.

17. The Department (or Florida Blue; the terms may be used interchangeably) again denied [redacted] appeal. The Department's basis for its denial was stated thusly:

> The *State Employees' PPO Plan Group Health Insurance Plan Booklet and Benefits Document*, effective Jan. 1, 2015, states on page 15-3 under Definitions:
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> "Experimental or investigational services . . . any evaluation, treatment, therapy or device that meets any one of the following criteria:
>
> 1. Cannot be lawfully marketed without approval of the U.S. Food and Drug Administration or the Florida Department of Health, and approval for marketing in the United States has not been given at the time

the service is provided to the covered person; or

2. Is the subject of ongoing Phase I or II clinical investigation, or the experimental or research arm of a Phase III clinical investigation, or is under study to determine the maximum dosage, toxicity, safety or efficacy, or to determine the efficacy compared to standard treatment for the Condition; or

3. Is generally regarded by experts in the United States as requiring more study to determine maximum dosage, toxicity, safety or efficacy, or to determine the efficacy compared to standard treatment for the Condition; or

4. Has not been proven safe and effective for treatment of the Condition based on the most recently published medical literature of the United States, Canada or Great Britain using generally accepted scientific, medical or public health methodologies or statistical practices; or

5. Is not accepted in consensus by practicing Doctors in the United States as safe and effective for the Condition; or

6. Is not regularly used by practicing Doctors in the United States to treat patients with the same or a similar Condition.

Florida Blue, CVS/Caremark, and DSGI [Division of State Group Insurance] determine whether a service or supply is Experimental or Investigational."

(Emphasis added).

18. The denial portion of the Department's letter concluded:

"The ReWalk™ exoskeleton system is not a covered item because the system is the subject of at least two Phase I clinical trials." (Emphasis added). That is, the ReWalk was excluded from coverage under the Plan not because it was on the list of specifically excluded services, but because it met one of the criteria for determining whether it was an experimental or investigational service, specifically Criterion 2.

19. The denial letter then went on to explain [redacted] right to appeal the denial and the process for doing so, including the right to request a formal administrative hearing.

20. Section 5 of the Plan addresses the services and supplies which are excluded from coverage. One of the excluded services is:

> Experimental or investigational services, prescription drugs and procedures as determined by Florida Blue, CVC/Caremark and DSGI, or services, prescription drugs and procedures not in accordance with generally accepted professional medical standards, including complications resulting from those non-covered services.

The denial letter appears to classify ReWalk as an "experimental or investigational service."

21. Following receipt of the Department's restated basis for denying her request for approval of a ReWalk system, [redacted] filed the petition for formal administrative hearing which is the genesis of this proceeding. In her request for a

formal hearing, [redacted] again asserted that the ReWalk is not "the subject of at least two Phase I clinical trials." That is, she refuted the basis of the Department's denial letter.

22. At final hearing, [redacted] presented the testimony of an expert in spinal cord injuries. The expert, Dr. Vanni, is a Board-certified neurological surgeon, specializing in patients with spinal cord injuries. He is the Chief of Spinal Neurology at Jackson Memorial Hospital and has published numerous articles in that field. Dr. Vanni gives lectures, trains residents, and stays current on literature related to spinal cord injuries. However, as noted by the Department, Dr. Vanni has testified previously about the ReWalk and has been paid for doing so by [redacted] counsel, ReedSmith. His testimony was nonetheless very credible and is afforded significant weight.

23. Dr. Vanni explained the nature of spinal cord injuries and the treatment for such injuries. A person suffering such injury may lose sensory or motor functions, or both. The person would need assistance in all aspects of daily living due to many potential issues, e.g., bowel and bladder loss, inability to feel when sitting, skin sores, loss of muscle tone and bone structure, psychological issues, and extreme and/or chronic pain. Being bedridden or confined to a wheelchair can exacerbate each of these conditions.

24. ReWalk is one of several exoskeletons available for persons with spinal cord injuries. It received approval by the FDA in 2014 and was approved for use by the Veterans' Administration in 2015. ReWalk is already used by over 1,000 patients at more than 80 rehabilitation centers worldwide. At the Miami Project to Cure Paralysis, at which Dr. Vanni works full time with spinal cord injury patients, exoskeletons are used extensively. Dr. Vanni considers the ReWalk to be a beneficial treatment for spinal cord injury patients. He specifically considers it medically necessary treatment for [redacted] corroborating her treating physician's opinion.

25. Dr. Vanni cited to a number of medical studies addressing the ReWalk system. Many of those had small sample sizes, i.e., only a few patients were reviewed, but the reason for that is that there are not large numbers of spinal cord patients for whom an exoskeleton might be useful. Thus, necessarily, the tested groups are smaller than studies concerning other health-related products or treatments. While the Department expresses concern about the smaller groups and considers results from those studies inadequate, the most persuasive evidence was that the studies should be considered. Dr. Vanni pointed out the significant findings in many of the studies and considered the studies, in his expert opinion, reliable. The studies included the following:

The Miller meta-analysis (2016) used 14 studies looking at robotic exoskeletons within the past four years for 111 patients. The study found many benefits, including cardiac activity, exercise tolerance, and bowel improvements, from use of the exoskeleton. The devices were found to be safe and allowed patients to ambulate in real-world settings. ReWalk funded this analysis.

The Federici study (2015) reviewed 27 different small case studies with 114 participants, finding improvement of the patients' functioning.

The Stampacchia study (2016) looked at the psychological and physical impacts on 27 participants using robotic exoskeletons, with very beneficial results.

The Platz study (2016) looked at using unpowered orthoses, e.g., mechanical hip, knee or foot orthosis as training tools. The study shows that exoskeletons have a major advantage over passive orthosis, i.e., something that just holds a patient's joint in position. This was also a small case study: seven individuals over one to 24 weeks, each.

The Esquenazi study (2012) addressed 12 participants utilizing an exoskeleton versus lower limb braces and found no safety issues or concerns and many benefits. The study found that ReWalk could "in the future" offer users a great level of independent upright mobility.

The Zeilig study (2012) was a small case series of six individuals which resulted in a finding of no significant falls, no inner joint injuries or cardiovascular incidents. However, a larger study would be necessary to demonstrate efficacy. This study was also funded by ReWalk.

> The (second) Miller study (2016) focused on the financial impact of using an exoskeleton, i.e., that the improved physical activity for patients using the device translated into fewer overall health issues, thus lower health-related costs.

26. Dr. Vanni admitted that larger numbers of participants in the studies could result in more accurate conclusions. Nonetheless, as it is impossible to find large numbers of spinal cord injury patients who could be appropriate subjects in the studies, it is necessary to rely on the data that can be assembled. And, he concluded, the available data demonstrates that ReWalk is not experimental or investigational at this point in time.

27. Dr. Hudec is the Department's designated expert concerning whether a service or medical treatment is covered under the Plan. The process he employs involves use of clinical information to determine whether there is a covered benefit under the Plan. He would then determine whether the service is medically necessary. Dr. Hudec is admittedly not Board-certified in neurology, nor does he have any practical experience or training in the area of spinal cord injuries. He therefore does not stay current on literature addressing spinal cord injuries, except as it might apply to surgery. From a strictly professional perspective, Dr. Hudec's testimony relating to the treatment of spinal cord injuries is given less

weight than the testimony of Dr. Vanni.[1/] While Dr. Hudec is a respected physician in his own right, his training and experience in the area of medicine at issue is less than Dr. Vanni's.

28. Dr. Hudec pointed out that ReWalk had not actually been tested in a home or work environment for [redacted] usage, but had been tested only in a "laboratory" environment. A trained assistant was present at the tests, something [redacted] might not have access to at home. Thus, he reasoned, the testing that had occurred to date was inadequate. [redacted] pointed out that she would have to become familiar with the device in a clinical setting before using it at home or on the job. Also, many of the studies cited above involved testing on various terrains.

29. [redacted] has, in fact, been able to "test drive" the ReWalk at the local HealthSouth rehabilitation clinic. The company which produces ReWalk shipped devices to HealthSouth Rehab Center in Tallahassee numerous times for inspection and testing by prospective users. The Department contends that because the ReWalk was only available in Tallahassee (with the next closest availability being Atlanta or South Florida), it is obviously not very common and, therefore, is "experimental or investigational." There was no other evidence offered to support that contention. Dr. Vanni, on the other hand, noted

that exoskeletons are used extensively at the Jackson Memorial Hospital in Miami. And, he noted, if it were more available even more physicians would likely recommend it for their patients.

30. [redacted] was able to walk with assistance from the ReWalk the very first time she tried it, despite warnings that it may take several attempts. She has used it half a dozen times in various ways, i.e., standing and sitting, traveling over different terrains and outdoors as well as indoors. What she found was that when she walked for about 45 minutes with the ReWalk, her chronic burning pain would disappear for up to 36 hours. This result was consistent with studies which suggest exoskeletons can result in less spasticity of muscles and be beneficial to bowel issues. [redacted] relied on trained staff when testing the ReWalk; she would hire someone to train as an assistant and/or use her spouse or children if the device is approved for her home use.

31. Dr. Hudec surprisingly and frankly testified that Criterion 2--which had been cited by the Department as its basis for denial of [redacted] request--did not apply to [redacted] case. He said, instead, that Criteria 3, 5, 6, and perhaps 4, could support the Department's contention that ReWalk is "experimental or investigational." The Department's own nurse consultant contradicted Dr. Hudec, saying that the ReWalk was

the subject of two Phase I trials, i.e., the Criterion 2 basis for denial.

32. Dr. Hudec relies in part on two policies or policy statements created by the BCBS Association entitled, Power Exoskeleton for Ambulation in Patients with Lower Limb Disabilities. While he cannot say precisely why the policies were created by BCBS Association, Dr. Hudec considers them valid and instructional. In his capacity as the Florida representative of BCBS Association, Dr. Hudec contributes to the development and interpretation of policies for that entity. When Florida Blue does not have a policy statement regarding a particular service, it will look to BCBS Association policies in order to maintain consistency with regard to coverage. As will be discussed below, however, there seems to be a wide disparity between the various BCBS affiliates concerning what is covered.

33. The BCBS Association policy statements generally find that exoskeletons--and specifically ReWalk--have potential to assist patients to ambulate (obviously) but also can be beneficial for other health outcomes as well. Some of the peripheral positive outcomes include better bowel and bladder function, help with spasticity, and improved cardiovascular health for users of the device.

34. The BCBS Association policies conclude that while there are many positive benefits created by ReWalk, the test

groups that were used to measure outcomes were fairly small. Thus, reasoned BCBS, there should be more studies done in order to more fully verify the results reached. Dr. Hudec accepted those conclusions as the basis for his opinion that ReWalk should not be covered under the Plan. Florida Blue does not have a specific policy regarding exoskeleton usage, but attempts to remain consistent with the BCBS Association policies.

35. Dr. Hudec summarized his opinion that ReWalk is not covered under the Plan thusly: 1) That the device was still being tested in a controlled, laboratory setting rather than in a home or workplace; 2) That the testing required the presence of a trained clinician or spotter during the training; 3) That the number of participants in the case studies was small and thus less conclusive; and 4) That there were no long-term studies to examine whether people using the device could do so safely over a period of time. These factors convinced Dr. Hudec that ReWalk is experimental or investigational, whether or not Criterion 2 was utilized in the analysis. Dr. Hudec did not quantify the length of time the studies would have to be performed in order to alleviate his concern about them being "short term" in nature. However, that another brand of exoskeleton was approved by FDA in 2006 is some indication that the devices have been studied for quite some time.

36. While not completely accepting the Department's right to change its very basis for denial of [redacted] appeal at final hearing, the other criteria mentioned by Dr. Hudec will be nonetheless addressed. Ms. Flippo, who reviews Level II appeals for Florida Blue, discussed her approach to the five criteria. She said that once she finds that one of the criteria applies, she simply stops her review. Therefore, she did not consider Criteria 3 through 6 at all in her review. Based upon the general thoroughness of review set forth in the materials provided, her testimony is not persuasive as to that point. It seems highly unlikely Florida Blue would give such short shrift to the remaining criteria, i.e., not considering each of them. Besides, the Department had relied on Criteria 2 as the only basis for denial in [redacted] Level II appeal, as set forth in its denial letter. The late reference to the other criteria (at final hearing) seems somewhat contrived and inappropriate.

37. Criterion 3 looks at whether the item at issue is "generally regarded by experts as requiring more study." Dr. Hudec said some studies have concluded that ReWalk is safe, but other studies say further study is needed. He did not qualify or quantify the "studies" he was relying upon, but concluded ReWalk is "not generally regarded by experts." Dr. Hudec based his opinion, in large part, on his understanding that no other major insurance plan has approved the ReWalk.

A number of plans do provide coverage for ReWalk, however, including the Veterans' Administration (which has the largest single network of spinal cord injury care in the nation), BCBS Vermont, BCBS Illinois, BCBS Federal Employee Plan, Tri-Care, Common Ground Health Plan, and Massachusetts Health.[2/]

38. Dr. Hudec did not discuss how other BCBS plans under the general umbrella of BCBS Association differ from Florida Blue. But Dr. Hudec noted that none of what he called the "bigger" health plans, e.g., CIGNA, AETNA, Humana, have yet approved coverage for the ReWalk. According to Dr. Hudec, the larger groups must consider the ReWalk experimental or investigational in nature. No non-hearsay evidence was presented to support his conclusion.

39. The Department's expert nurse consultant, Kathi Flippo, pointed out that other plans may have different definitions which they are applying. If so, that could be the reason they approved the ReWalk, even though it is deemed inappropriate under the Plan in Florida. Again, there was no non-hearsay evidence presented to support her supposition as to why other groups have not yet approved ReWalk.

40. Criterion 5 talks of a drug or device "not accepted by consensus by practicing doctors in the United States." In response to that criterion, Dr. Hudec reasoned that since the request at issue is the only request for ReWalk received by the

Department, it must not be "accepted by consensus" by other United States doctors. Otherwise, he opined, Florida Blue would have received more results. His testimony did not address the limited universe of patients under Florida Blue who might benefit from the ReWalk, i.e., whether there have been no other requests because there has not been a determination of medical necessity for the product for policy holders. Nor did he address whether other insurance providers may have received requests for exoskeletons. Nurse Flippo personally knows of at least one other person in Tallahassee who has requested approval of a ReWalk. Dr. Hudec's testimony and rationale that fewer requests equates to lack of consensus among doctors is not persuasive.

41. Similarly, Criterion 6 speaks of devices and drugs "not regularly used by doctors in the United States to treat patients." Dr. Hudec restated his testimony from Criterion 5, and it still fails to be persuasive. Nurse Flippo added that if the Department does not see a lot of requests for exoskeletons, doctors must not deem them safe. There is no competent evidence in the record to support that speculative logic.

42. Dr. Hudec equivocated as to whether Criterion 4 could be a basis for denial of [redacted] claim. He said the criterion could be applied if the Plan was interpreted to preclude the ReWalk, i.e., just because FDA approved the device

does not mean that the Plan must follow suit. The testimony was insufficient to prove that Criterion 4 applies in this case.

43. Dr. Fuhrmeister, [redacted] treating physician, said the ReWalk was medically necessary for [redacted] due to her condition. Dr. Hudec did not attempt to refute Dr. Furhmeister's decision concerning [redacted] treatment as he does not critique other physician's decisions about their patients. Medical necessity, he opined, is between the patient and their doctors.

44. Despite Dr. Hudec's conclusions to the contrary, the ReWalk and other exoskeleton devices have been studied extensively. They have been tested in different environments and on many different individuals. They are already used extensively even as testing continues. Dr. Vanni's affirmation of the ReWalk studies provides persuasive evidence that exoskeletons (including ReWalk) are no longer "experimental or investigational."

45. Even if the ReWalk was approved under the Plan, the Department would not cover all of the costs involved. As ReWalk is a non-network provider under the Plan, the member [redacted] would be responsible for paying the deductible and then 40 percent of the allowable cost, and the Plan would pay the remaining 60 percent. Coverage would be limited to the "standard model" of ReWalk exoskeleton unless an upgrade was

determined to be medically necessary. Further, any education or training on the exoskeleton device is a Plan exclusion and would not be covered by the Plan.

CONCLUSIONS OF LAW

46. The Division of Administrative Hearings has jurisdiction over the parties to and the subject matter of this proceeding pursuant to Sections 120.569 and 120.57(1), Florida Statutes. Unless specifically stated otherwise herein, all references to Florida Statutes will be to the 2016 version.

47. [redacted] has the initial burden of proof in this matter as she is asserting the affirmative of the issue. Balino v. Dep't of HRS, 348 So. 2d 349 (Fla. 1st DCA 1977).

48. The standard of proof is by a preponderance, or greater weight, of the evidence. See Dep't of Banking & Fin. v. Osborne Stern & Co., 670 So. 2d 932, 934 (Fla. 1996); and section 120.57(1)(j)("Findings of fact shall be based upon a preponderance of the evidence, except in penal or licensure disciplinary proceedings or except as otherwise provided by statute.")

49. A preponderance of evidence is defined as "the greater weight of the evidence" or evidence that "more likely than not" tends to prove a certain proposition. Gross v. Lyons, 763 So. 2d 276, 280 (Fla. 2000).

50. In these cases, if the petitioner meets their burden, the burden would then shift to the state agency to prove that the requested relief was not covered due to a policy exclusion. See Young v. Dep't of Cmty. Aff., 625 So. 2d 831 (Fla. 1993); Herrera v. C.A. Seguros Catatumbo, 844 So. 2d 654, 668 (Fla. 3d DCA 2003); State Comp. Health Ass'n v. Carmichael, 706 So. 2d 319, 320 (Fla. 4th DCA 1997).

51. [redacted] met her burden by proving that the ReWalk is medically necessary and would be beneficial to her health.

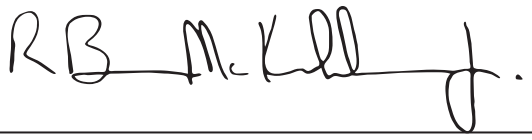
52. The Department contends ReWalk is experimental or investigational and is thus excluded from coverage under the Plan, because it "[i]s the subject of ongoing Phase I or II clinical investigation." However, the Department withdrew its argument concerning Phase I or II clinical investigation at final hearing, thus obfuscating its basis for denial of approval for the ReWalk.

53. The remaining bases for denial of approval, i.e., Criteria 3 through 6, were proven to be inapplicable by a preponderance of evidence. The Department made general, speculative assumptions which were not persuasive. While the Department proved that the ReWalk is a fairly recent innovation, [redacted] proved by a preponderance of evidence that it is not still experimental or investigational.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that a final order be issued by the Department of Management Services, Division of State Group Insurance, approving Petitioner, [redacted] [redacted] request for coverage of a ReWalk system under the State Employees' Preferred Provider Organization insurance plan.

DONE AND ENTERED this 7th day of June, 2017, in Tallahassee, Leon County, Florida.



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Filed with the Clerk of the
Division of Administrative Hearings
this 7th day of June, 2017.

ENDNOTES

[1/] Essentially, Dr. Hudec's opinions are valid only to the extent the literature he relied upon was legitimate, consistent with the standards of medical practice, and accurate. He was not, based on his background and training, able to independently verify any of those criteria for the studies he reviewed.

[2/] [redacted] actually pointed out a number of other, smaller providers which have approved exoskeletons, including: Tufts

Health Plan; Matrix; Absence Management; New Mexico Municipal League; State Compensation Insurance Fund of California; Ohio Bureau of Workers' Compensation; Patriot Care Management; Patriot Health; Britt and Associates, LLC; Wirth and Associates, LLC; Liberty Mutual; High Mark Blue Shield; and Farm Bureau.

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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.