UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

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| JAMES JOHNSON,<br><br>Plaintiff,<br>vs.<br><br>WELLMARK OF SOUTH DAKOTA, INC. d/b/a/ WELLMARK BLUE CROSS AND BLUE SHIELD OF SOUTH DAKOTA,<br><br>Defendant. | **CIV. 19-4017-LLP**<br><br>**MEMORDANDUM OPINION AND ORDER DENYING MOTION FOR SUMMARY JUDGMENT** |

This case concerns a claim for long-term disability benefits under an employee welfare benefit plan governed by ERISA. Pending before the Court is Defendant Wellmark of South Dakota, Inc.'s ("Wellmark") Motion for Summary Judgment (Doc. 26) and Plaintiff James Johnson's Motion for Determination of Medical Necessity (Doc. 29). For the following reason's Wellmark's Motion for Summary Judgment is denied. The Court will address in a separate opinion Johnson's Motion for Determination of Medical Necessity.

## BACKGROUND

### A. Injury and FES Cycle

On August 12, 2017, Johnson was severely injured after the all-terrain vehicle that he was driving entered a ditch and rolled near his home in Beresford, South Dakota. (Docs. 1, ¶ 7; 23, WELLMARK 979.) Johnson was rushed to the hospital and was diagnosed with two fractured vertebrae at the C5/6 levels. (Doc. 23, WELLMARK 981.) Johnson underwent emergency surgery on his spine. (Doc. 23, WELLMARK 981.) Although Johnson eventually regained some use of his arms, he did not regain any use of his legs. (Doc. 23, WELLMARK 982.) Johnson is classified as a level C5 ASIA A tetraplegia which means he has no motor or sensory function below his level of injury. (Doc. 23, WELLMARK 917.) At the time Johnson was injured, he was an employee of Southeast Farmers Coop and paid premiums to be a covered beneficiary to the employer sponsored group health insurance plan issued by Wellmark.

After Johnson's surgery in South Dakota, he was transferred to Madonna Rehabilitation Hospital in Lincoln, Nebraska ("Madonna Rehabilitation") to attend intensive inpatient rehabilitation treatment. (Doc. 23, WELLMARK 961.) On September 21, 2017, Johnson's board-certified physician, Dr. Paul Krabbenhoft; physical therapist, Janelle Hansen, PT; and occupational therapist, Danielle Willey, OT of Madonna Rehabilitation prescribed the RT300 functional electrical stimulator cycle ("the FES Cycle") for Johnson. (Doc. 23, WELLMARK 960-61.) The Cycle is a neuromuscular electrical stimulation device that Johnson used during his rehabilitation at Madonna Rehabilitation. (Doc. 23, WELLMARK 961-964.)

After Dr. Krabbenhoft prescribed the FES Cycle, Madonna Rehabilitation submitted the claim to Wellmark with medical documentation to confirm Johnson's progress from the Cycle while at Madonna Rehabilitation. (Doc. 23, WELLMARK 960-964.) In his Letter of Medical Necessity dated September 21, 2017, Dr. Krabbenhoft stated that:

> James utilizes a standing frame weekly to maintain leg and trunk flexibility, as well as reaping the benefits from weight bearing and upright positioning of his body. James also needs to undertake an alternative form of activity therapy since he has lost the ability to do this volitionally. This is medically necessary to maintain his physical condition and to minimize concomitant medical complications, which can have serious health consequences and be costly to resolve.
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> Once a patient has sustained a spinal cord injury and is stabilized, upper and lower extremity mobilization can be achieved by use of a cycle ergometer powered by a patient's own muscle strength evoked by FES. Based on the level and nature of his injury, our experience indicates that James would benefit from a continued program of upper and lower extremity movement utilizing RT300.
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> James has been evaluated on RT300 and has an excellent response while trialing it at Madonna Rehabilitation Hospital in Lincoln, Nebraska. James' peripheral never supply is intact allowing him to respond to RT300's electrical stimulation.
>
> James has cycled 22 number of sessions to date, including both upper and lower extremity cycling sessions, and is able tolerate 48-50 minutes of treatment without fatigue limitations. During a lower extremity cycling session, 6.49 miles of FES cycling were accomplished at 35 revolutions per minute. Other outcome measures achieved were average energy expenditure of 9.6 kilocalories/hour and average power output of 11.4 Watts. James and his spouse Katie demonstrate a commitment to pursue and FES activity regimen in his home setting; both have received training and Katie has demonstrated her ability to independently complete management of the cycling equipment and James' set-up assist needs.

With electrical stimulation James is able to achieve strong, coordinated muscle contractions in the shoulders and arms as well as his legs (including gluteal and abdominal muscles). This positive upper and lower extremity response to electrical stimulation is supportive of future benefits of an FES home program. Future benefits of FES cycling have been well documented over the last 25 years of research and most recently also been tracked in RT300 home patients.

RT300 is an integrated FES system, which provides a complex rehabilitation treatment, RT300 is a class II medical device which carries multiple FDA clearances . . . for rehabilitation of the following indications:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Maintaining or increasing range of motion

RT300 provides intense electrical stimulation (*current up to 140mA)* below the level of James' neurologic injury. This level of electrical stimulation is the amount of current required to evoke a strong muscle contraction in a neurologically impaired person and is beyond the level which would be tolerated by a person without a neurologic disease or disability. RT300 is **NOT** utilized by persons without disease or disability nor will it have any profound effect on a person without disease or disability who is able to achieve activity volitionally. The electrical stimulation achieves a strong, coordinated muscle contraction in James' arms and legs creating a therapeutic dosage of intensive movement and patterned neural activity which James would not otherwise to able to obtain. The safety, efficacy and economy of the RT300 cycle ergometer are superior to conventional therapies such as passive movement.

Injury to the spinal cord causes profound immobility and inactivity in the upper and lower extremities that in turn leads to several physical and metabolic changes detrimental to James' health. These changes include a decrease in muscle mass, muscle atrophy, increase in whole body fat, decreased muscle endurance, decreased lower extremity bone density, spasticity, limited joint ROM ["range of motion"] and compromised circulation. These changes can lead to further complications such as skin breakdown (decubitus ulcers), thromboembolic disease, diabetes, recurrent urinary tract infections, and increase in risk of fractures, and early cardiovascular disease. . . Research from over 70 peer reviewed and established journals such as *Spinal Cord*, *Archives of Physical Medicine and Rehabilitation*, *American Journal of Physiology*, *Neurosurgery*, and *Clinical Orthopedics* has demonstrated that the use of the an upper and lower extremity FES cycle ergometer, RT300, has been proven as a safe an effective tool for the management and prevention of these changes in individuals with a spinal cord injury.

> Research has shown that the benefits of FES cycling include: increase in muscle cross sectional area, muscle hypertrophy and capillarization, increases in lean body mass with a decrease in whole body fat content, increases in muscle endurance, increases in muscle output, increases in bone density, improved oxygen uptake, improvements in body's utilization of oxygen (typically 20-35%), improvement in heart rate, improved cardiac stroke volume, improved cardiac output during activity and pronounced effect on cardiovascular health at rest, lead to significant positive changes in spasticity and increased in knee flexion range of motion.
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> . . .
>
> RT300 also has the capacity to stimulate James' trunk muscles to enhance the overall effectiveness and benefits that FES cycling provides. The lack of voluntary control of the trunk muscles can have serious functional and health-related implications for those with SCI. The inability to vary seated posture or maintain anything other than one passive stable position can lead to skeletal deformities, increased risk for development of decubitus ulcers and impositions of large and non physiological pressure on internal organs that may compromise their function. In healthy individuals, the erector spinae (back muscles) provide trunk extension and are the primary means of achieving stability and balance of the head and trunk during sitting. After spinal cord injury (SCI), paralysis of the erector spinae diminishes or eliminates voluntary trunk control, leading to dramatic changes in seated posture and the ability to grasp objects bimanually. Patients with tetraplegia often have respiratory complications because of paralysis of the abdominal and intercostal muscles. The abdominal muscles are powerful muscles for expiration, playing an important role in functions such as forced expiration and coughing. The reduction in peak flow affects the ability to clear the airways leading to an increased likelihood of respiratory infections in individuals with chronic tetraplegia. A study by Gollee et al. shows that FES using surface electrodes placed in the abdominal wall can significantly improve tidal volume and cough peak flow and significantly improve respiratory function in tetraplegic subjects. Furthermore assisting the patients to cough helps to clear bronchial secretions more effectively and in the long run could help prevent respiratory infections.

(Doc. 23, WELLMARK 962-964.) Dr. Krabbenhoft also stated that benefits and goals sought to be achieved by use of the FES Cycle could only be reached by using the FES Cycle at least three times per week and as such, Johnson must receive RT300 FES therapy at home. (Doc. 23, WELLMARK 964.) Dr. Krabbenhoft states "[a]long with his compliance, James has begun to show improvements and would benefit from muscle conditioning, joint range of motion, management of spasticity and other physical integrity benefits from continued used of the RT300 FES ergometer." (Doc. 23, WELLMARK 1068.) Dr. Krabbenhoft stated that "[g]ood medical

practice requires that suitable patients be prescribed FES cycle ergometry in order to protect their health by preventing the secondary complications that would otherwise inevitably arise as a result of the spinal cord injury and immobility." (Doc. 23, WELLMARK 964.)

In his letter of medical necessity, Dr. Krabbenhoft cited thirty medical studies that he contends show the following benefits: a) two studies show increases in muscle cross sectional area; b) three studies show muscle hypertrophy and one study shows muscle capillarization; c) one study shows reduced vascular resistance and one study shows improved blood flow; d) two studies show increases in lean body mass and one study shows a decrease in whole body fat content; e) four studies show increases in muscle endurance, output; f) three studies show increases in bone density at the hip, distal femur and proximal tibia; g) one study shows decreases in complications such as skin breakdown and thromboembolic disease; h) one study shows improved glucose tolerance and insulin sensitivity; i) one study shows increase insulin sensitivity; j) one study shows improved oxygen uptake; k) five studies show improvements of the body's utilization of oxygen, typically 20-35%; l) one study shows improvements in heart rate, stroke volume, and cardiac output during exercise and at rest indicating a pronounced effect on cardiovascular health; m) two studies show FES cycling with a large number of repetitions (greater than 1500 per week) lead to significant positive changes in spasticity; n) one study shows reduced spastic muscle tone with FES cycling as compared to passive cycling; and o) one study shows increases in knee joint range of motion. (Doc.23,WELLMARK965.)

**Wellmark's Denial and Johnson's First Appeal**

On January 13, 2018, Wellmark denied Johnson's claim. (Doc. 23, WELLMARK 1378.) In its Explanation of Benefits, it characterized the FES Cycle as "Home Medical Equipment" and stated that Johnson was responsible for the full amount of the Cycle, $21,755.00. (Doc. 23, WELLMARK 1378.) It is unclear to the Court the reason provided by Wellmark for the denial. In his first appeal, Johnson stated that the FES Cycle was denied on January 13, 2018, "as experimental, investigation, unproven and exercise equipment." (Doc. 23, WELLMARK 1046.) However, the Explanation of Benefits in the record simply states that: "You may be missing out on savings that you would receive if services had been performed by a Blue Cross and Blue Shield participating provider." (Doc. 23, WELLMARK 1378.)

On March 8, 2018, Johnson sent his first letter of appeal to Wellmark. Therein, Johnson provided a list of other insurance plans across the country, including Wellmark[1], that have approved the RT300 for members who are "unfortunate victims of neurologic injury and disease." (Doc. 23, WELLMARK 1046.) In addition, Johnson noted that there are no in-network providers of the RT300 FES Cycle Therapy System because Restorative Therapies is the sole manufacturer and distributor of the RT300. (Doc. 23, WELLMARK 1046.) Johnson also stated that the FES Cycle has received FDA clearance for the following indications: prevention or retardation of disuse atrophy, relaxation of muscle spasms, maintaining or increasing range of motion, and increasing local blood circulation and that he struggles with these on a daily basis. (Doc. 23, WELLMARK 1047.) Johnson referenced the list of peer-reviewed studies included by Dr. Krabbenhoft in his Letter of Medical Necessity. (WELLMARK 1051.) In his appeal, Johnson also included an additional summary outlining the health and wellness benefits of the FES Cycle with supporting references and a list of 34 randomized/controlled studies of the FES Cycle which he states show positive functional changes and short and long-term health and fitness benefits in spinal cord injured patients. (Doc. 23, WELLMARK 1051.) Johnson stated that over 200 peer-reviewed publications have examined the outcomes of FES cycling. (Doc. 23, WELLMARK 51.) He acknowledges that many of the studies utilize subjects as their own controls instead of a randomized study design because of the low incidence of neurologic injury and disability compared to asthma or diabetes and, as such, says that it would be unreasonable for Wellmark to only consider randomized study designs when reviewing his case. (Doc. 23, WELLMARK 1051.)

In his letter of appeal, Johnson notes that the FES Cycle has been adopted for use by over 250 leading spinal cord injury rehabilitation centers around the country, including, but not limited to: Shephard Center in Atlanta, Georgia; Craig Hospital in Englewood, Colorado; National Rehabilitation Hospital in Washington, D.C.; Johns Hopkins Kennedy Krieger Institute in Baltimore, Maryland; Magee Rehabilitation Hospital in Philadelphia, Pennsylvania; Spaulding Rehabilitation Hospital in Boston, Massachusetts; Boston University Medical Center in Boston, Massachusetts; Kessler Institute for Rehabilitation in West Orange, New Jersey; University of Washington Medical Center in Settle, Washington; University of Michigan Medical Center in Ann Arbor; Mount Sinai Medical Center in New York, New York; Courage Centers in Minnesota;

[1] There is no indication that any of the Wellmark entities that approved coverage of the FES Cycle were Wellmark of South Dakota, Inc.

Shriners Hospitals for Children; Rehabilitation Institute of Michigan in Detroit; University of Alabama at Birmingham; VA Healthcare System. (Doc. 23, WELLMARK 1051.) Johnson stated that many of these centers are Model System Centers for Spinal Cord Injuries as designated by the National Institute of Disability Rehabilitation and Research (NIDRR). (Doc. 23, WELLMARK 1052.) Johnson explained that the Model Centers provide leadership and establish protocols for the delivery, demonstration, and evaluation of comprehensive medical, vocational, and other rehabilitation services to meet the needs of individuals with SCI. (Doc. 23, WELLMARK 1052.) Johnson further stated that the FES Cycle is widely accepted by the SCI professional medical community as an effective and proven rehabilitative treatment and is widely accepted at Model SCI System Centers, Opinion Leading SCI Centers, Acute Treatment and Rehabilitation Hospitals, Physical Therapy Facilities, and Military Hospital Systems across the United States, Canada, Europe, and Australia as part of their inpatient/outpatient/acute care/long-term care/polytrauma units and at-home rehabilitative therapy and disease management programs. (Doc. 23, WELLMARK 1052.)

Johnson stated that without this active-based therapy around 3 times per week, it can be expected that he would experience a growing number of secondary medical complications because of chronic immobility including: "pressure sores, diabetes, osteopenia with risk of fractures, blood lipid disorders, recurrent urinary tract infections, spasticity, joint stiffness, and early cardiovascular disease." (Doc. 23, WELLMARK 1053.) Johnson stated that he has no other options outside of the FES Cycle that will allow him to achieve muscle contractions below this level of injury. (Doc. 23, WELLMARK 1053.) Johnson stated that active therapy provided by the FES Cycle is superior to conventional therapies such as passive movement, i.e. when a patient's arms and legs are moved mechanically by a therapists' hands or a machine. (Doc. 23, WELLMARK 1053.) Johnson explained that passive therapy does not create muscle contractions and does not deliver any of the benefits of FES Cycling that he achieves when his muscles are doing the work and completing movements under volitional control or activated by the FES Cycle. (Doc. 23, WELLMARK 1053.). Johnson cited a study showing that passive cycling does not alter arterial leg blood flow in patients with SCI and does not prevent cardiovascular-related secondary complications. (Doc. 23, WELLMARK 1053.)

**B. Wellmark Plan and Medical Policy**

The Coverage Manual is the "contract" describing Johnson's right and responsibilities under his group health plan." (Doc. 23, WELLMARK 7.) Benefits that are covered and that are excluded from coverage are detailed therein. (Doc. 23, WELLMARK 17.) In its Explanation of Benefits, the FES Cycle is designated as Home Medical Equipment which is defined in the plan as equipment that meets all of the following requirements: (1) durable enough to withstand repeated use; (2) primarily and customarily manufactured to serve a medical purpose; (3) used to serve a medical purpose. (Doc. 23, WELLMARK 28.) However, in its "Conditions of Coverage," the Plan provides that "[e]ven a service, supply, device, or drug listed as otherwise covered in *Details – Covered and Not Covered* may be excluded if it is not medically necessary in the circumstances." The Coverage Manual defines "medically necessary" as follows:

> A medically necessary health care service is one that a provider, exercising prudent clinical judgment, provides to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and is:
>
> - Provided in accordance with generally accepted standards of medical practice. Generally accepted standards of medical practice are based on:
>   - Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community;
>   - Physician Specialty Society recommendations and the views of physicians practicing in the relevant clinical area; and
>   - Any other relevant factors.
> - Clinically appropriate in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease.
> - Not provided primarily for the convenience of the patient, physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the illness, injury or disease.
>
> An alternative service, supply, device, or drug may meet the criteria of medical necessity for a specific condition. If alternatives are substantially equal in clinical effectiveness and use similar therapeutic agents or regimens, we reserve the right to approve the least costly alternative.

(Doc. 23, WELLMARK 43.) The Coverage Manual explicitly provides that "[a]ll covered services are subject to the terms and conditions contained throughout [the] coverage manual." (Doc. 23, WELLMARK 17.) The Coverage Manual also informs plan participants such as Johnson that "[t]o fully understand which services are covered and which are not, [they] must become familiar with this entire coverage manual." (Doc. 23, WELLMARK 17.)

Wellmark has a medical policy that characterizes the FES Cycle as being not medically necessary. Specifically, it provides that the RT300 FES cycle ergometer is considered home exercise equipment even when being used for muscle atrophy, and therefore, not medically necessary for all indications. (Doc. 23, WELLMARK 146.) With regard to the RT300, the medical policy provides as follows:

> The FES Cycle Therapy System (RT300) is described as a neuromuscular electrical stimulation device to reduce spasticity or facilitate voluntary motor control in individuals with spinal cord injury. There is insufficient evidence that electrical neuromuscular stimulation provides any long term benefit in the rehabilitation of spinal cord patients. The evidence for decreasing contracture, preventing muscle loss or improving exercise capacity above and beyond that of simple rehabilitative techniques has not been proven. Exercise is beneficial and recommended but the equipment to perform exercise is not considered a medical necessity. The device is considered not medically necessary.

(Doc. 23, WELLMARK 146-47.) The Coverage Manual references Wellmark's medical policies in the section providing that "Investigational or Experimental" treatment is excluded from coverage. (Doc. 23, WELLMARK 43-44.) That section informs plan participants that they may find Wellmark's medical policies on its website, *Wellmark.com*, but provides that decisions regarding "Investigational or Experimental" status are made at the discretion of Wellmark's Medical Director "whose decision is not controlled by policies or decisions of other Blue Cross and Blue Shield member organizations." (Doc. 23, WELLMARK 44.)

**C. Denial of First Appeal**

On April 9, 2018, the Medical Review Institute of America, LLC, an external reviewer, performed a review of Johnson's first appeal. (Doc. 23, WELLMARK 1398.) The physician performing the review was board certified by the American Board of Physical Medicine & Rehabilitation in General Physical Medicine & Rehabilitation and Pain Medicine. (Doc. 23, WELLMARK 1399.) The physician reviewer was a member of the American Academy of Physical Medicine and Rehabilitation, and the American Medical Association, and has been in active practice since 2008. (Doc. 23, WELLMARK 1399.) The reviewer addressed the following questions: (1) Does the patient's conditions meet the submitted medical policy criteria for the requested service; FES Cycle Therapy System RT300 (CPT Code E1399)?; and (2) Describe

specific reasons for overturning the original denial and/or for upholding the original denial. (Doc. 23, WELLMARK 1396.) In addressing those questions, the physician reviewer provided:

> The treating provider has ordered a RT300 FES ergometry system, which is a neuromuscular electrical stimulation device for the prevention and retardation of muscle disuse atrophy, relaxation of muscle spasms, increasing local blood circulation, and maintaining and increasing range of motion. The device provides intense electrical stimulation to peripheral nerves below the level of neurologic injury to evoke a strong muscle contraction, creating a therapeutic dosage of intense movement and patterned neural activity. The device allows a person with impaired upper or lower motor extremity movement to participate in cycle ergometry with active movement. Use of the device would decrease the complications from chronic immobility, including muscle atrophy, diabetes, decreased lower extremity bone density, and compromised circulation.
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> The patient has been evaluated on the requested device with an excellent responsible [sic], trialing its use at the Madonna Rehabilitation Hospital in Lincoln, Nebraska. His peripheral nerve supplies are intact, allowing him to respond to the device's electrical stimulation. He has cycled 22 sections to date including both the upper and lower extremities and was able to tolerate 48 to 50 minutes of treatment without fatigue limitations. With the electrical stimulation, the patient is able to achieve strong coordinated muscle contractions in the shoulders and arms as well as his legs.

(Doc. 23, WELLMARK 1395-96.)

Wellmark denied Johnson's appeal, stating, in part, as follows:

> The Official Disability Guidelines (ODG)[2] do not recommend devices approved as exercise equipment, such as the RT300 motorized FES Cycle Therapy System for extremity weakness. The requested device is not clinically appropriate in terms of type, frequency, extent, site and duration, or considered effective for the patient's illness, injury or disease. The requested device is not clinically appropriate since the quality of the current studies is too poor to draw any substantial conclusions about the effect of FES treatment for spinal cord injury. There is no high quality evidence in the medical literature that the requested device is less costly and more and as effective than alternative, standard rehabilitative treatments.

[2] The Official Disability Guidelines for Treatment of Workers Comp ("ODG") compiles and reports disability duration and return to work data emanating from four federal databases. *Ranavaya v. Work Loss Data Institute,* LLC, Civ. No. 05-0109, 2006 WL 2469113, at *1 (S.D. W.Va. Aug. 24, 2006). ODG was published by Work Loss Data Institute, LLC ("WLDI"). *Id.* ODG is sold on a subscription basis and licenses the ODG for internal case management and claims systems. *Electronic Waveform Lab Inc. v. Work-Loss Data Institute, LLC*, Civ. No. 15-0794, 2015 WL 12684232, at *1 (C.D. Cal. Aug. 25, 2015). Insurance carriers use the ODG entries to determine whether to cover certain treatments. *Id.* In 2017, WLDI was acquired by Hearst and then became part of MCG Health. *See* www.mcg.com/odg/about-odg/our-history-work-loss-data-institute/ (last accessed Nov. 17, 2020).

> The requested device does not meet the medical policy's definition of an approved functional electrical stimulation (FES) device. See answer for question 1. The medical policy (01.01.23 defines FES (functional electrical stimulation) as devices used to enhance functional activity in neurologically impaired patients. The objective of FES is to activate targeted muscle groups to facilitate performance of functional activities (e.g., grasping utensils for feeding) or movements (e.g., ambulation). The requested RT300 FES ergometry system for the member does not meet the medical policy definitions of FES (functional electrical stimulation) devices since it is not used to facilitate performance of functional activities, such as ambulation.
>
> The medical policy (01.01.23) states that the FES Cycle Therapy System (RT300) is described as a neuromuscular electrical stimulation device to reduce spasticity or facilitate voluntary motor control in individuals with spinal cord injury. There is insufficient evidence the electrical neuromuscular stimulation provides any long term benefit in the rehabilitation of spinal cord patients, so the RT300 FES ergometry system is considered not medically necessary. The requested device for the member is a RT300 FES ergometry system. Since the RT300 FES ergometry system is listed as a device considered by the medical policy as home exercise equipment and not medically necessary, the requested device for the member does not meet medical policy criteria. The denial should be upheld.

(Doc. 23, WELLMARK 1398.) It is noted by the Court that much of the last paragraph quoted above is taken directly from Wellmark's medical policy on the RT300 FES ergometry system. The references that the physician reviewer cited to support his decision were the 2018 Official Disability Guidelines on Functional Electrical Stimulation and Lu X, Battistuzzo CR, Zoghi M, Galea MP. *Effects of training on upper limb function after cervical spinal cord injury: a systematic review*. Clinical Rehabilitation 2015 Jan; 29(1);3-13. (Doc. 23, WELLMARK 1398-99.)

**D. Johnson's Second Appeal**

Pursuant to the terms of the Policy, Johnson requested an external review through the South Dakota Insurance Division. The South Dakota Insurance Division selected National Medical Reviews, Inc. as the independent review entity. (Doc. 23, WELLMARK 921.) In his external appeal, Johnson iterated many of the same points made in his first level appeal. Johnson reiterated that the FES Cycle is the only therapy that allows him to activate his own muscles below his level of injury. (Doc. 23, WELLMARK 932.) In addition, Johnson provided that:

> There is [ ] scientific evidence in peer-reviewed literature that supports a result of improvement in health outcome. A review (Sujith) indicates that FES has been shown to result in improvement in voluntary strength, decrease in energy cost, decrease in osteopenia, among other benefits. (Needham-Shropshire et al.)

reported a study of 34 subjects (including controls) that showed FES was effective for improving motor function.

A most recent study of 45 subjects was done in 2013 by Kennedy Krieger Institute's International Center for Spinal Cord Injury[3] (Sadowsky et al.) which found that FES cycling was a practical form of physical activity that provided substantial benefits, including improved physical integrity, advanced neurological and functional performance, increased muscle size and strength, reduced muscle spasticity and improved quality of life.

In addition, there are many articles regarding effects on bone density. These articles support the maintenance and increase in bone density as a result of FES cycling. In particular, a study by (Frotzler) demonstrated bone loss reversal with FES cycling. And a follow-up study by the same research group showed these bone density improvements were maintained up to a year after the intervention was ceased.

References:


- Duffel et al., Muscle Nerve 2008; 38(4); 1304-11
- Chilbeck et al., Spinal Cord 1999; 37(4); 264-8
- Bremner et al., Paraplegia 1992; 30(9); 647-55
- Donaldson et al. Spinal Cord 2000; 38(11); 680-2
- Sujith OK. "Functional electrical stimulation in neurologic disorders." EUR J Neurol, 2008; 15: 437-444.
- Needham-Shropshire BM, et al. "Improved motor function in tetraplegics following neuromuscular stimulation assisted arm ergometry." J Spinal Cord Med, Vol. 20, Number 1, 1997.
- Sadowsky et al. FES cycling promotes recovery The Journal of Spinal Cord Medicine 2013, VOL. 0, NO. 0
- Frotzler et al. Bone 2008, Jul; 43(a):169-76
- Frotzler et al. J Rehabil Med 2009; 33(1);68-72


A 2008 study (Krause et al. Clin Rehabil 2008 Jul; 22(7):627-34) demonstrated that FES cycling improves spasticity outcomes far superior than passive intervention. In fact, there are other studies that illustrate that limitations of passive motion interventions in the SCI population (Woerds et al. Physical Therapy 2006; 86 (5):636-45).

(Doc. 23, WELLMARK 1130-31.)

**E. Denial of Johnson's Second Appeal**

On August 28, 2018, National Medical Reviews, Inc. upheld the decision to deny Johnson coverage for the FES Cycle. (Doc. 23, WELLMARK 915.) The physician who reviewed Johnson's second appeal is board certified in physical medicine and rehabilitation, pain medicine

[3] Located at John's Hopkins University.

and spinal cord injury medicine. (Doc. 23, WELLMARK 919.) The physician reviewer is an associate clinical professor of physical medicine and rehabilitation for a facility in Massachusetts, has special clinical interest in musculoskeletal medicine, traumatic brain injury, spasticity management, disability evaluation, impairment evaluation and utilization review, and has over 15 years of clinical experience. (Doc. 23, WELLAMARK 929.)

The physician reviewer addressed whether the RT300 FES cycle was medically necessary for the "treatment" of Johnson's condition. (Doc. 23, WELLMARK 918). The physician reviewer's response was as follows:

> No. In terms of recovery after spinal cord injury, most recovery occurs in the first six to 12 months. However, recovery can extend beyond one year, and neurologic recovery continues for perhaps up to two years. In this case, the member is two years status post injury and further neurological recovery is unlikely.
>
> The member has an upper level cervical spinal cord injury. In 10/2017 he had partial preservation of muscle strength on his right side.
>
> Although there are no reported episodes of autonomic dysreflexia or pressure ulcers, use of the requested RT300 FES Cycle System would carry potential risks of pressure ulcer formation, autonomic dysreflexia, post-exercise hypotension, thermal dysregulation, as well as other musculoskeletal injuries. In this case, although not a reported current problem, there is a history of hypotension during his acute rehabilitation.
>
> In terms of function abilities, at this level of injury, the member may be able to use adapted conventional equipment for strengthening. His documented upper extremity strength in 10/2017 is consistent with being able to use an adapted upper extremity or wheelchair ergometer for cardiovascular exercise. He is already using a standing frame.
>
> The RT 300 FES cycle system would not treat the member's spinal cord injury and is being requested as a preventative measure and means of exercise. Although exercise is beneficial and highly recommended, it is considered no more medically necessary in this case than for any other individual. It is not medically necessary for the treatment of this member's condition.

(Doc. 23, WELLMARK 918.) The physician reviewer cited the following references he used in support of his or her decision: 1) BeDell, KK, et al. Effects of functional electrical stimulation-induced lower extremity cycling on bone density of spinal cord injured patients. American Journal of Physical Medicine and Rehabilitation, 1996; 75:29-34. 2) CMS Decision Memo for Neuromuscular Electrical Stimulation for Spinal Cord Injury (CAG-00153 R), July 22, 2002; 3) Hooker, SP et al. Physiologic response to prolonged electrically stimulated leg-cycle exercise in

the spinal cord injury. Archives of Physical Medicine and Rehabilitation 1990; vol 71: 863-869; 4) O'Sullivan SB Schmitz U. Physical Rehabilitation: Assessment and Treatment, 5th ed. F.A. Davis Co., 2007; 5) Vernon Lin MD PhD (Editor), Spinal Cord Medicine: Second Edition: Principles & Practice. Demos Medical, 2010. (Doc. 23, WELLMARK 919.)

**F. Procedural History**

On January 23, 2019, Johnson filed a complaint in federal district court alleging that "[Wellmark's] refusal to pay [him] benefits violates the terms of the Plan." (Doc. 1.) On May 15, 2019, Wellmark filed a Motion seeking to limit the case to the ERISA administrative record (Doc. 10) which the Court granted in part and denied in part in its Memorandum Opinion and Order dated February 27, 2020 (Doc. 20). On August 17, 2020, Wellmark filed a Motion for Summary Judgment (Doc. 26) and Johnson filed a Motion for Determination on Medical Necessity (Doc. 29). These motions have been fully briefed by the parties and are ready for disposition. The Court will now address Wellmark's Motion for Summary Judgment and will address Johnson's Motion for Determination on Medical Necessity in a separate opinion.

## DISCUSSION

### I. SUMMARY JUDGMENT

In support of its Motion for Summary Judgment, Wellmark argues that: 1) the FES Cycle is excluded from coverage under the terms of Johnson's plan; and 2) the FES Cycle is not "medically" necessary under the terms of the plan.

**A. Standard of Review**

An administrator's denial of ERISA benefits is reviewed under either a *de novo* or abuse of discretion standard. For the reasons set forth in the Court's February 27, 2020 Order, Johnson's claim will be reviewed *de novo*. Doc. 20. Under *de novo* review, "[t]he court simply proceeds to evaluate whether the plan administrator correctly or incorrectly denied benefits." *Abatie v. Alta Health & Life Ins. Co.*, 458 F.3d 955, 963 (9th Cir. 2006).

In its February 2020 Order, the Court found that while the First and Tenth Circuit Court of Appeals have held that courts may grant summary judgment despite disputed material facts in the administrative record, *see Orndorf v. Paul Revere Life Ins. Co.*, 404 F.3d 510, 517 (1st Cir. 2005)

(describing summary judgment as the "vehicle" to resolve ERISA benefit disputes); *LaAsmar v. Phelps Dodge Corp. Life, Accidental Death & Dismemberment & Dependent Life Ins. Plan*, 605 F.3d 789, 796 (10th Cir. 2010), it concluded that this approach is inconsistent with Rule 56 of the Federal Rules of Civil Procedure which requires the Court to view all facts in the light most favorable to the non-moving party and grant all reasonable inferences in his favor. This Court agreed with the Second and Ninth Circuit Courts of Appeals that have held that courts must deny summary judgment when the administrative record reflects factual discrepancies. *See*, *O'Hara v. Nat'l Union Fire Ins. Co.,* 642 F.3d 110, 116 (2d Cir. 2011); *Kearney v. Standard Insurance Company,* 175 F.3d 1084, 1094 (9th Cir. 1999).

Accordingly, summary judgment in this case is appropriate if the movant "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). To meet this burden, the moving party must identify those portions of the record which demonstrate the absence of a genuine issue of material fact, or must show that the nonmoving party has failed to present evidence to support an element of the nonmovant's case on which it bears the ultimate burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). Once the moving party has met this burden, "[t]he nonmoving party may not 'rest on mere allegations or denials, but must demonstrate on the record the existence of specific facts which create a genuine issue for trial.'" *Mosley v. City of Northwoods, Mo.*, 415 F.3d 908, 910 (8th Cir. 2005) (quoting *Krenik v. Cty. of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995)). "[T]he mere existence of some alleged factual dispute between the parties is not sufficient by itself to deny summary judgment. . . . Instead, the dispute must be outcome determinative under prevailing law." *Id.* at 910-11 (quoting *Get Away Club, Inc. v. Coleman*, 969 F.2d 664, 666 (8th Cir. 1992)). In ruling on a motion for summary judgment, the facts, and inferences drawn from those facts, are "viewed in the light most favorable to the party opposing the motion" for summary judgment. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (citation omitted).

**B. Is the FES Cycle Excluded from Coverage under the Plan's Terms?**

ERISA allows a beneficiary to bring a civil action "to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan." 29 U.S.C. § 1132(a)(1)(B). In support of its summary

judgment motion, Wellmark argues that the benefits sought by Johnson (the FES Cycle Therapy System (RT300)) are not "due to [Johnson] under the terms of his plan" because the FES Cycle is explicitly excluded from coverage under Wellmark's medical policy and Johnson's plan terms. Doc. 27 at 3. Wellmark denied the claim on the basis that the FES cycle is home exercise equipment that does not rehabilitate spinal cord injuries, citing to its medical policy related to such devices. (Doc. 23, WELLMARK 1396-1398). Wellmark states that these medical policies are available to members and explicitly referenced in both the Group Insurance Policy and the Coverage Manual. (Doc. 23, WELLMARK 44, 118). Wellmark argues that the exclusion of the FES Cycle is thus "part of the contractual bargain struck when Johnson obtained coverage under the Plan." Doc. 27 at 4.

"When reviewing an ERISA plan de novo, [the courts] interpret the terms of the plan by giving the language its common and ordinary meaning as a reasonable person in the position of the plan participant, not the actual participant, would have understood those words to mean." *Adams v. Continental Cas. Co.*, 364 F.3d 952, 954 (8th Cir. 2004) (quotations omitted). A court is to begin "by examining the language of [the plan] documents, keeping in mind that each provision should be read consistently with the others as a part of an integrated whole." *Kitterman v. Coventry Health Care of Iowa, Inc.*, 632 F.3d 445, 448 (8th Cir. 2011) (quotations omitted).

The Coverage Manual is the "contract" describing Johnson's right and responsibilities under his group health plan. (Doc. 23, WELLMARK 7). Benefits that are covered and that are excluded from coverage are detailed therein. (Doc. 23, WELLMARK 17.) Wellmark argues that its medical policies, including the policy excluding coverage for the FES Cycle, are incorporated by reference and into the Coverage Manual and thus govern whether the FES Cycle prescribed to Johnson is medically necessary. Doc. 27 at 2. This Court disagrees.

The only mention made of Wellmark's medical policies is not in the section defining a "Medically Necessary" health care service, but in the section excluding from coverage "Investigational or Experimental" treatment. (Doc. 23, WELLMARK 43-44.) The Court notes that in the present case, Wellmark denied coverage on the basis of "medical necessity," not on the basis that the FES Cycle is "investigational or experimental." Regardless, the Court finds that under the plain language of the plan's terms, Wellmark's medical policies are not binding on coverage decisions. Johnson's plan specifically provides that with regard to determining

investigational or experimental status, Wellmark may refer to the technical criteria established by the Blue Cross and Blue Shield Association, but that "the final decision remains at the discretion of Wellmark's Medical Director, whose decision is not controlled by policies or decisions of other Blue Cross or Blue Shield member organizations." (Doc. 23, WELLMARK 44.)

Moreover, contrary to that argued by Wellmark, the Court does not find that language in the Group Insurance policy referencing Wellmark's medical policies affects Johnson's coverage under the terms of his plan. Specifically, Wellmark cites to language in the Group Insurance Policy by and between Wellmark and the plan sponsor/group policyholder (Johnson's employer) providing that "Wellmark shall determine benefits and process Incurred Claims for health services furnished members in accordance with the . . . medical policies of Wellmark." Doc. 27 at 2 (citing Doc. 23, WELLMARK 118.) Johnson is not a party to this contract. Rather, the Group Insurance Policy delineates the rights and responsibilities of Wellmark and the plan sponsor/group policyholder (Johnson's employer). While the Group Insurance Policy generally provides that Wellmark is responsible for determining benefits for health plan members in accordance with the Coverage Manual's terms and Wellmark's medical policies, nothing in this agreement alters the specific terms of the Coverage Manual by and between Johnson and Wellmark. The Coverage Manual makes clear that "[a]ll covered services are subject to the contract terms and conditions contained throughout this coverage manual." (Doc. 23, WELLMARK 17.) "To understand which services are covered and which are not," the Coverage Manual directs plan participants such as Johnson to "become familiar with this entire coverage manual," but does not direct Johnson to consult the Group Insurance Policy that his employer entered into with Wellmark.

The Court finds that neither the language of the Coverage Manual, nor any amendments or modifications thereto that are in the record before the Court, provide that "Medical Necessity" determinations are made in accordance with Wellmark medical policies. For these reasons, the Court denies Wellmark's Motion for Summary Judgment on the basis that the FES Cycle is excluded from coverage under Wellmark's medical policies.

**C. Medical Necessity**

Wellmark also argues that it is entitled to summary judgment on the basis that the FES Cycle is not "medically necessary" under the terms of the plan. While the Court agrees that the

FES Cycle qualifies under the terms of the plan as home/durable medical equipment,[4] in its "Conditions of Coverage," the Coverage Manual provides that "[e]ven a service, supply, device, or drug listed as otherwise covered in *Details – Covered and Not Covered* may be excluded if it is not medically necessary in the circumstances." (Doc. 23, WELLMARK 43.) The Coverage Manual defines "medically necessary" as follows:

> A medically necessary health care service is one that a provider, exercising prudent clinical judgment, provides to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and is:
>
> - Provided in accordance with generally accepted standards of medical practice. Generally accepted standards of medical practice are based on:
>  - Credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community;
>  - Physician Specialty Society recommendations and the views of physicians practicing in the relevant clinical area; and
>  - Any other relevant factors.
> - Clinically appropriate in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease.
> - Not provided primarily for the convenience of the patient, physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the illness, injury or disease.
>
> An alternative service, supply, device, or drug may meet the criteria of medical necessity for a specific condition. If alternatives are substantially equal in clinical effectiveness and use similar therapeutic agents or regimens, we reserve the right to approve the least costly alternative.

(Doc. 23, WELLMARK 43.) Wellmark argues that the FES Cycle is not "medically necessary" under the terms of Johnson's plan because it was not prescribed "for the purpose of preventing, evaluating, diagnosing, or treating an illness, injury, disease or its symptoms." Doc. 27 at 5. In his Letter of Medical Necessity, Johnson's physician, Dr. Paul Krabbenhoft, stated that the FES Cycle is "an alternative form of activity therapy . . . to maintain [Johnson's] physical condition and minimize concomitant medical complications . . . ." (Doc. 23, WELLMARK 961.) Therein, Dr. Krabbenhoft also stated that the benefits of the FES cycle are: "increase in muscle cross

[4] The Coverage Manual defines Home/Durable Medical Equipment as equipment that meets all of the following requirements:

- Durable enough to withstand repeated use.
- Primarily and customarily manufactured to serve a medical purpose.
- Used to serve a medical purpose.

(Doc. 23, WELLMARK 28.)

sectional area, muscle hypertrophy and capillarization, increases in lean body mass with a decrease in whole body fat content, increases in muscle endurance, increases in muscle output, increases in bone density, improved oxygen uptake, improvements in body's utilization of oxygen (typically 20-35%), improvement in heart rate, improved cardiac stroke volume, improved cardiac output during activity and pronounced effect on cardiovascular health at rest . . . significant positive changes in spasticity and increased in knee flexion range of motion." (Doc. 23, WELLMARK 963.) Wellmark argues that language used by Dr. Krabbenhoft in his Letter of Medical Necessity supports a finding by this Court that the FES Cycle "would not treat [Johnson's] spinal cord injury and is [instead] being requested as a preventative measure and means of exercise." Doc. 27 at 5.

In opposition, Johnson argues that the definition of "medical necessity" adopted in the Coverage Manual is extremely broad and "includes coverage for the prevention of illness, injury, disease or symptoms that occur with an illness, injury, or disease." Doc. 32 at 6. Johnson argues that:

> [T]he [FES] Cycle is only utilized by persons with disabilities or disease for relaxation of muscle spasms (which qualifies as treatment of an injury or its symptoms), prevention or retardation if disuse atrophy (which qualifies as prevention of an injury or its symptoms), increasing local blood circulation (which qualifies as prevention or treatment of an injury or its symptoms), and maintenance or increase of a person's range of motion (which qualifies as prevention or treatment of an injury or its symptoms).

Doc. 32 at 6. Johnson argues that people with Johnson's spinal cord injury experience physical and metabolic changes that are detrimental to their health, including "decrease in muscle mass, muscle atrophy, increase in whole body fat, decreased muscle endurance, decreased lower extremity bone density, spasticity, limited joint ROM [range of motion] and compromised circulation." Johnson characterizes these potential complications as symptoms of Johnson's spinal cord injury and argues that the FES cycle is "medically necessary" within the plan's terms because it prevents and treats Johnson's spinal cord injury and its symptoms. Doc. 32 at 6. Johnson also argues that the FES Cycle "mitigates, treats and prevents those adverse effects and 'allows muscle contractions and workload to maintain muscle and bone health and improve metabolism . . . prevents early onset CAD [Coronary Artery Disease] or Diabetes (Type 2).'" Doc. 32 at 6.

Construing the facts in the light most favorable to Johnson and drawing all inferences in his favor, the Court must now determine whether Wellmark is entitled to summary judgment on

the basis that the FES Cycle is not medically necessary under the terms of Johnson's plan. In doing so, the Court will focus primarily on whether the FES Cycle is prescribed "for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms." (*See* Doc. 23, WELLMARK 43.) As stated above, "[w]hen reviewing an ERISA plan *de novo*, [the court] interpret[s] the terms of the plan by giving the language its common and ordinary meaning as a reasonable person in the position of the plan participant, not the actual participant, would have understood those words to mean." *Adams v. Continental Cas. Co.*, 364 F.3d 952, 954 (8th Cir. 2004) (quotations omitted); *Brewer v. Lincoln Nat'l Life Ins. Co.*, 921 F.2d 150, 154 (8th Cir. 1990) (stating that an ERISA plan's terms "should be accorded their ordinary, and not specialized, meaning[].").

The Court notes at the outset that it disagrees with Johnson's argument that the plan covers benefits for the prevention of the "symptoms" of an injury such as Johnson's spinal cord injury. The plain language of Johnson's plan limits coverage for health services to those directed at preventing and treating a "disease and its symptoms," not an injury and its symptoms. Although the plan does not define "disease," the Court does not find that Johnson's spinal cord injury constitutes a "disease" within the plain meaning of the term. A "disease" is defined by the Cambridge Dictionary as an "illness or people, animals, plants, etc., caused by infection or failure of health rather than by an accident." Definition of disease, *Cambridge Dictionary*, *available at* dictionary.cambridge.org. There is no dispute that Johnson's spinal cord injury resulted from his ATV accident rather than an infection or failure of health and thus does not fall within the plain meaning of "disease."

Under the terms of Johnson's plan, "medically necessary" health care services do include those provided for the treatment or prevention of an injury, or a disease and its symptoms. The Court finds that some of the complications listed by Johnson that may arise from chronic inactivity associated with tetraplegia, including Cardiovascular Disease and Type II diabetes, are considered to be "diseases." Although the Plan does not define the meaning of "injury," the Oxford English Dictionary defines "injury" as "hurt or loss caused to or sustained by a person or thing" and the Cambridge Dictionary defines "injury" as "hurt, damage, or loss sustained." Definition of injury, *Cambridge Dictionary*, *available at* dictionary.cambridge.org and *Oxford English Dictionary*, available at www.oed.com. The Court finds that these definitions of "injury" encompass some of

complications listed by Johnson from chronic inactivity associated with tetraplegia such as pressure sores, urinary tract infections, and spasticity. The fact that an injury or disease develops as a result of, or during the course of, a primary injury or disease does not, under the plain language of the plan, exempt it from coverage.

Wellmark argues that Johnson seeks coverage simply for home exercise equipment. While this Court agrees that a broad range of health care services may be prescribed for the "purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms," the Court notes that the plain language of the plan excludes coverage for Home Durable Medical Equipment for items used for a plan participant's "personal convenience." (Doc. 23, WELLMARK 29.) The Plan defines "Personal Convenience Items" as:

- Items not primarily and customarily manufactured to serve a medical purpose or which can be used in the absence of illness or injury (including, but not limited to, air conditioners, dehumidifiers, ramps, home remodeling, hot tubs, swimming pools); or
- Items that do not serve a medical purpose or are not needed to serve a medical purpose.

(Doc. 23, WELLMARK 45.) Johnson is not seeking coverage for home exercise equipment that may be utilized by able-bodied persons. The record is clear that the FES Cycle is classified as a Class II medical device and is not used by persons other than those who, like Johnson, have sustained a spinal cord injury.

In sum, given the plain meaning of the plan's terms, the Court cannot say as a matter of law that the FES Cycle was not prescribed to Johnson for the purpose of preventing or treating an injury or disease.

**D. Other Medical Necessity Factors**

In addition to "preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms," in order for the FES Cycle to be considered "medically necessary" under the terms of the Plan, the Cycle must meet these other conditions: 1) be provided in accordance with generally accepted standards of medical practice; 2) be clinically appropriate in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and 3) not be provided primarily for the convenience of the patient, physician, nor more costly than an alternative service at least as likely to produce equivalent therapeutic or diagnostic

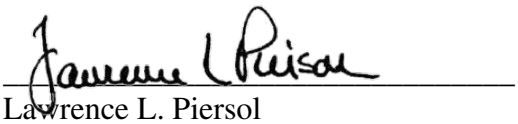
results as to the diagnosis or treatment of the illness, injury or disease. (Doc. 23, WELLMARK 43.)

Wellmark's argument, which has been rejected by this Court, is that the FES Cycle is not medically necessary home/durable medical equipment because it is not used to "prevent, evaluate, diagnose, or treat an illness, injury, disease or its symptoms." Doc. 35 at 2. In its memorandum in support of its summary judgment motion, Wellmark does not address whether the FES Cycle meets the other conditions of "medical necessity" detailed in the Plan—i.e., whether it was provided in accordance with generally accepted standards of medical practice; was clinically appropriate; and was not for the convenience of the patient nor more costly than an alternative service as likely to produce equivalent therapeutic results. Wellmark acknowledges in its Reply Brief that it has not addressed these other medical necessity requirements because they only come "into play once the prior conditions set out in the medical necessity have been met;" only if the FES Cycle is found by the Court to prevent, evaluate, diagnose, or treat an illness, injury, disease or its symptoms. Doc. 35 at 2. The Court is unable to find as a matter of law that the FES Cycle fails to meet the definition of "medical necessity" detailed in the Plan. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986) (holding that in order to prevail on summary judgment, the moving party must identify those portions of the record which demonstrate the absence of a genuine issue of material fact, or must show that the nonmoving party has failed to present evidence to support an element of the nonmovant's case on which it bears the ultimate burden of proof).

Accordingly, it is hereby ORDERED that Wellmark's Motion for Summary Judgment, Doc. 26, is DENIED.

Dated this 8th day of December, 2020.

BY THE COURT:



Lawrence L. Piersol
United States District Judge

ATTEST:
MATTHEW W. THELEN, CLERK