ATTACHMENT A

THE PROPOSED DECISION
BEFORE THE
BOARD OF ADMINISTRATION
CALIFORNIA PUBLIC EMPLOYEES' RETIREMENT SYSTEM
STATE OF CALIFORNIA

In the Matter of the Appeal Regarding Denial of Benefit Coverage for the Purchase of an ARPWave Machine for:

TIMOTHY E. RAMOS,

Respondent.

Case No. 2017-0851
OAH No. 2018010106

PROPOSED DECISION

This matter was heard by Erin R. Koch-Goodman, Administrative Law Judge, Office of Administrative Hearings, State of California, on May 23, August 14, and September 27, 2018, in Sacramento, California.

Rory J. Coffey, Senior Attorney, represented the California Public Employees' Retirement System (CalPERS).

Timothy E. Ramos (respondent) appeared by telephone and represented himself.

Evidence was received, the record closed, and the matter submitted for decision on September 27, 2018.

ISSUE

Did Anthem properly deny respondent's benefit coverage for the purchase of an ARPWave Rx100 machine (HCPCS\(^1\) E0764)?

\(^1\) HCPCS, Healthcare Common Procedure Coding System, was developed by the Centers for Medicare and Medicaid; the system is used by healthcare professionals, including medical coders and billers.
FACTUAL FINDINGS

1. CalPERS is the agency charged with administering the Public Employees' Medical and Hospital Care Act (PEMHCA) pursuant to Government Code section 22750 et seq. PEMHCA authorizes and requires the Board of Administration of CalPERS to provide health benefits for state employees, dependants, annuitants, as well as for employees and annuitants of contracting public agencies which elect to contract with CalPERS for health benefit coverage.

2. PERS Care Health Plan (PERS Care or Plan) is a preferred provider health plan offered by CalPERS to individuals eligible for health care benefits under PEMHCA. CalPERS contracts with Anthem Blue Cross (Anthem) to administer PERS Care medical claims. Anthem Utilization Management Services Inc. (AUM) provides utilization management services for Anthem and Anthem Blue Cross Life and Health Insurance Company.

3. At all times relevant, respondent was eligible for CalPERS health benefits under PEMHCA because of his employment with the California Department of Corrections and Rehabilitation (CDCR) as a correctional officer. On November 9, 2002, respondent disability retired from his position with CDCR.

4. On October 14, 2016, ARPWave, LLC submitted a letter to Anthem requesting pre-determination/prior authorization for durable medical equipment (DME) for respondent: an ARPWave Rx100 machine (ARPWave). On October 17, 2016, and October 18, 2016, AUM sent respondent a letter, denying authorization for the purchase of the ARPWave. On October 27, 2016, respondent appealed to Anthem, requesting a review of the denial. On November 9, 2016, and November 18, 2016, Anthem sent respondent a letter, upholding AUM's determination denying authorization of coverage for the ARPWave. On December 9, 2016, respondent contacted Anthem and requested an independent external review; Anthem contracted with Network Medical Review (NMR) for an Independent Medical Review (IMR). On January 9, 2017, NMR sent respondent a Notice of Independent Review Decision, upholding Anthem's denial of coverage for the ARPWave.

6. The PERS Care, Evidence of Coverage (EOC) 2017, effective January 1 to December 31, 2017, sets forth the conditions of the Plan, including those pertaining to benefits, claims and payment of claims. The Plan provides coverage “only for those services that are determined to be Medically Necessary; however, even Medically Necessary services are subject to the Benefits Limitations, Exceptions and Exclusions section.” (EOC 2017, Medically Necessary, pg. 23.)

“Medically Necessary” services are procedures, treatments, supplies, devices, equipment, facilities or Drugs (all services) that a qualified Health Professional, exercising prudent clinical judgment, would provide to a covered individual for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- in accordance with generally accepted standards of medical practice (i.e., standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, national Physician specialty society recommendations and the views of medical practitioners practicing relevant clinical areas and any other relevant factors); and

- clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the covered individual’s illness, injury or disease; and

- not primarily for the convenience of the covered individual, 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 that covered individual’s illness, injury or disease.

The fact that a provider may prescribe, order, recommend or approve a service, supply, or hospitalization does not in itself make it Medically Necessary. The Plan reviews services to assure that they meet the medical necessity criteria above. The Plan’s review processes are consistent with processes found in other managed care environments and are consistent with the
Plan’s medical and Pharmacy policies. A service may be determined not to be Medically Necessary even though it may be considered beneficial to the patient.

(Ibid.)

7. The Plan does not provide for convenience items, non-standard services and supplies, and experimental or investigational practices or procedures. (EOC 2017, Benefit Limitations, Exceptions and Exclusions, pp. 74-75.)

Convenience Items and Non-Standard Services and Supplies. Services and supplies determined by the Plan as not Medically Necessary or not generally furnished for the diagnosis or treatment of the particular illness, disease or injury; or services and supplies which are furnished primarily for the convenience of the Plan Member, irrespective of whether or not prescribed by a Physician.

Experimental or Investigational. Experimental or Investigational practices or procedures, and services in connection with such practices or procedures. Costs incurred for any treatment or procedure deemed by Anthem Blue Cross Medical Policy to be experimental and investigational ... are not covered.

(Ibid.)

8. The Plan defines Experimental or Investigational as:

Any treatment, therapy, procedure, Drug or Drug usage for non-FDA approved indications, facility or facility usage, device or device usage, or supplies which are not recognized in accordance with generally accepted professional medical standards as being safe and effective for use in the treatment of an illness, injury, or condition at issue. Additionally, any services that require approval by the federal government or any agency thereof, or by any state governmental agency, prior to use, and where such approval has not been granted at the time the services were rendered, shall be considered experimental or investigational. Any services that are not approved or recognized as being in accord with accepted professional medical standards, but nevertheless are authorized by law or by a government agency for use in testing, trials, or other studies on human patients, shall be considered experimental or investigational. Any issue as to whether a protocol, procedure,
practice, medical theory, treatment, or Prescription Drug is Experimental or Investigational will be resolved by Anthem Blue Cross or OptumRX, as applicable, which will have discretion to make an initial determination on behalf of the Plan.

Request for Coverage: ARPWave

9. Respondent is a 47-year-old man diagnosed with Multiple Sclerosis (MS), chronic pain, herniated discs, and muscle spasticity and atrophy. In 2014, respondent used the ARPWave for 30 days with good results, including decreased pain and reduced use of pain medications and muscle movement. On August 15, and December 1, 2015, Richard Covey, M.D., wrote an order for an ARPWave for respondent, listing respondent’s diagnoses as MS and muscle atrophy. In 2016, respondent used the ARPWave for 60 days with good results, including decreased pain and reduced use of pain medications and muscle movement. On October 13, 2016, respondent reported to Dr. Covey that the ARPWave eliminated the clonus (muscular spasm involving repeated, often rhythmic, contractions) when he woke in the morning.

10. On October 14, 2016, ARPWave sent a prior authorization request to Anthem, on respondent’s behalf, for an ARPWave Functional Neuromuscular Stimulator, HCPCS E0764. The ARPWave provides neuromuscular stimulation to increase range of motion and muscle strength and decrease pain. The classification E0764 is the Code for functional neuromuscular electric stimulation (NMES), transcutaneous stimulation of sequential muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program: also called Functional neuromuscular stimulation or functional electrical stimulation (FES).

11. On July 7, 2015, Leslie A. Friedman, M.D., neurologist, Department of Veteran’s Affairs (DVA), described the ARPWave machine as a medical necessity for respondent, because respondent has lower extremity weakness, spasticity, and significant pain related to his MS and the ARPWave is a method of analgesia for him. Respondent is a veteran and requested DVA cover the ARPWave; DVA denied coverage.

Reviews

12. On November 18, 2016, Anthem issued a denial letter, based upon the opinion of a neurologist, who reviewed respondent’s medical records and the Plan’s Medical Policy, specifically the section entitled Functional Electric Stimulation (FES); Threshold Electrical Stimulation (TES) (#DME.00022), and determined:

We cannot approve your request for a type of muscle treatment (functional electrical stimulation, also called FES)/ARP wave treatment. Your request tells us you have MS (multiple...
sclerosis/scarring of the nerves) causing weakness of your legs and foot drop. Medical studies do not show that FES will improve movement when your nerves are damaged in some way. For this reason we believe FES is investigational for you.

13. On December 13, 2016, NMR was asked to perform an IMR of the proposed care to determine if the adverse determination was appropriate. NMR assigned a Board Certified Neurology and Sleep Medicine Physician, who reviewed respondent’s clinical records, Plan provisions, and relevant guidelines and literature relating to the ARPWave. On January 9, 2017, NMR issued a Notice of Independent Review Decision, upholding Anthem’s denial, finding:

The ARPWave Therapy E0764 in this case would be experimental/investigational, inconsistent with standard of care, and would not be medically necessary.

The HCPCS code being used for the ARP Wave device would put it within the classification of a functional neuromuscular stimulator (FES) device. A search of current literature shows no results from any clinical trials with the specified device (ARP Wave). A review of the manufacturer’s website does not list any scientific publications specifically supporting the requested device in MS. The manufacturer’s website notes, “Outcomes for ARPWAVE Neuro Therapy have been based, thus far, on retrospective clinical observations. Randomized, double blinded, prospective studies have been initiated for the treatment of ankle sprains, hamstring injuries, and distal radius fractures. The hypotheses for these prospective studies is that ARPWAVE Neuro Therapy will yield recovery rates 60% to 80% faster than for traditional conservative treatment.

Given the absence of any primary source references on the use of this specific device, it can only be concluded to be experimental/investigational in nature.

The device appears to (possibly) be akin to a TENS unit. However, in a 2013 Cochrane [Database System] Review, Amatya et al, the authors concluded in the MS population, “No evidence of benefit exists to support the use of TENS, sports climbing, and vibration therapy for treating spasticity in this population.”

Ultimately, given the lack of published literature specific to the requested device and its algorithms, medical necessity cannot be established. The ARP Wave Therapy E0764 in this case would
be experimental/investigational, inconsistent with standard of care, and would not be medically necessary.

14. On June 2, 2017, CalPERS asked MAXIMUS to perform an IMR, using three Board Certified Neuromuscular Medicine Physicians, to decide if the ARPWave is medically necessary and/or experimental/investigational for treatment of respondent's medical conditions. MAXIMUS assigned three Board Certified Neuromuscular Medicine Physicians, who reviewed respondent's clinical records, relevant guidelines, and literature relating to the ARPWave. On June 13, 2017, MAXIMUS issued an IMR, upholding Anthem's denial, with two of the three physician reviewers finding that the ARPWave is not medically necessary and is experimental/investigational for the treatment of respondent's medical conditions.

- **MAXIMUS Physician #1**
The long-term use of ARP Rx100 device is not considered medically necessary for treatment of the patient's medical condition. The APR device is not in accordance with generally accepted standards of medical practice. There is a lack of medical literature supporting the use of the ARP device for treatment of the patient's symptoms of pain and spasticity. In addition, the medical records do not document that the patient has trialed clinically appropriate forms of electrical stimulation such as a TENS unit for treatment of his symptoms.

The requested long-term use of the ARP Rx100 device is considered experimental or investigational for treatment of the patient's medical condition. The ARP device is not recognized in accordance with generally accepted professional medical standards as being safe and effective for use in the treatment of the patient's medical condition. Moreover, there is a lack of medical literature showing the device to be effective in this clinical setting.

- **MAXIMUS Physician #2**
The long-term use of ARP Rx100 device is not considered medically necessary for treatment of the patient's medical conditions. The patient presents with multiple sclerosis, neurologic deficits and chronic pain related to spasticity in the lower extremities. The medical literature concerning the requested device focuses on athletic performance, rehabilitation and muscle mass maintenance. There is a lack of adequate double-blinded, prospective, randomized studies in the peer-reviewed literature demonstrating efficacy in pain management or for long-term improvement of spasticity related to neurologic
disease. Accordingly, the long-term use of [the] ARP Rx100 device is not medically necessary.

The requested long-term use of the ARP Rx100 device is considered experimental or investigational for treatment of the patient's medical condition. There is a lack of medical literature supporting the requested device as safe and effective for treatment in this clinical setting. The study by Amatya and colleagues assessed the effectiveness of various non pharmacological interventions for the treatment of spasticity in adults with multiple sclerosis. The authors noted that no evidence of benefit exists to support the use of transcutaneous electrical nerve stimulation (TENS). Furthermore, there is a lack of medical literature demonstrating ARP Rx100's efficacy in pain management or long-term improvement of spasticity related to neurologic disease. Accordingly, the requested device is experimental for treatment of the patient's medical condition.

- MAXIMUS Physician #3
  The long-term use of the ARP Wave Rx100 device is medically necessary for treatment of the patient's medical condition. The ARP Rx100 is a class II medical device approved by the U.S. Food and Drug Administration. The ARP device technology brings increased blood circulation into specific soft tissues along with enhanced reduction of scar tissue in the injured and atrophied muscles, immediately decreasing pain while increasing mobility and range of motion. This device is similar to [a] TENS unit and is commonly utilized to reduce pain. In this case, the patient presents with multiple sclerosis, chronic pain and herniated discs with reports of improvement and reduction in his use of pain medications. Given that the patient is likely to benefit from the long-term use of the ARP Rx100 device, the requested device is medically necessary for treatment of the patient's medical condition.

15. On July 21, 2017, Richard KP Sun, M.D., MPH, Medical Consultant, Health Plan Administration Division, CalPERS, sent respondent a letter upholding Anthem's denial of benefits. Dr. Sun provided 11 reasons, with supporting analysis, to uphold Anthem's denial of coverage.

(1) CalPERS accepts the June 13, 2017, MAXIMUS IMR reports of Physicians #1 and #2, who determined that the requested device is Experimental or Investigational and not Medically Necessary for treatment of your medical condition;
(2) CalPERS accepts the findings of the January 9, 2017, Independent External Review completed by Network Medical Review (NMR), which determined that the requested device is Experimental or Investigational and not Medically Necessary for treatment of your condition;

(3) CalPERS rejects the June 13, 2017, MAXIMUS IMR report of Physician #3;

(4) Medical policies of other managed care organizations indicate that ARPWave and similar devices are unproven, Experimental, Investigational, not covered, or not Medically Necessary;

(5) There is no mention of ARPWave in the Independent Medical Review database of the California Department of Managed Health Care;

(6) There is no mention of ARPWave in the UpToDate database;

(7) The studies you provided are irrelevant to your situation, and one is unpublished;

(8) We cannot find any peer-reviewed medical literature on the use of ARPWave in multiple sclerosis; for example, there is no mention of ARPWave in the PubMed database;

(9) For ARPWave to be considered Medically Necessary for pain and spasticity in multiple sclerosis, there must be a higher “level of evidence” (LOE);

(10) There is no HCPCS code precisely describing the device requested;

(11) The PERSCare Plan excludes “Non-Standard Services and Supplies.”

16. Finally, in May 2018, prior to hearing, CalPERS contracted with Claims Eval to perform an IMR, focusing on two issues: (1) given respondent’s clinical issues, is long-term use of the ARP Rx100 device considered Medically Necessary; and (2) if such use is not considered Medically Necessary, is long-term use of the ARP Rx100 device considered Experimental or Investigational? Claims Eval assigned three Board Certified Physicians, who reviewed respondent’s clinical records, relevant guidelines, and literature regarding the ARPWave. On May 16, 2018, Claims Eval issued three IMR reports, all finding the ARPWave is not medically necessary and is experimental/investigational for the treatment of respondent’s medical conditions.

• Claims Eval Physicians #1
  Despite FDA approval and submitted testimonials, evidence based medicine literature does not provide support for use of the ARP Wave for multiple sclerosis or spasticity. It is not known to be effective for the patient’s diagnosis of multiple sclerosis or symptoms of spasticity. Without evidence based medicine
literature supporting unit use, medical necessity is not evident. Recommendation does not represent clinically appropriate, prudent clinical judgment/treatment, as this is not in accordance with generally accepted treatment for multiple sclerosis or spasticity and is more costly than supported treatments. Therefore, medical necessity is not established.

Further, this request is considered experimental or investigational. Without quality evidence based upon medicine literature establishing the safety and efficacy of use for the diagnosis of multiple sclerosis and spasticity, it is not recognized as in accord with accepted professional medical standards despite FDA approval.

- Claims Eval Physician #2
  In this case, the requested treatment is not supported in evidence based medicine literature despite the numerous testimonials provided. Studies other than those by the manufacturer have not proven the outcomes noted in the testimonials and there are no quality studies demonstrating functional gains as a result of unit use. Therefore, the recommendation of this device does not represent prudent clinical judgment in treating the muscle spasticity associated with this patient’s multiple sclerosis. The use of [the] ARP device is not a generally accepted standard of medical practice, clinically appropriate or considered effective for this patient’s disease. It is more costly than [sic] alternative services. Given all factors, the criteria for medical necessity have not been met.

In this case, the device has been approved by the FDA, however, as it is not in accord with accepted professional medical standards and no evidence based medicine literature establishes its efficacy for spasticity due to multiple sclerosis, use remains experimental or investigational.

- Claims Eval Physician #3
  While the patient reports benefit from the use of the ARPWave device, this unit has not been shown to be effective in high-quality peer-reviewed literature and therefore does not demonstrate prudent clinical judgement in the provision of services for the patient’s multiple sclerosis diagnosis. The device was recommended by the patient’s treating providers for the purpose of treating the symptoms of multiple sclerosis, but evidence does not support that this is established as an effective
treatment for multiple sclerosis or the symptom of spasticity associated with this diagnosis. The ARPWave device is not a generally accepted standard of medical practice given the lack of evidence supporting its use. Treatment is not offered as a convenience but the cost of the service is more costly than alternatives.

Yes, the treatment is considered experimental or investigational. The definition of experimental and investigational includes “Any services which themselves are not approved or recognized as being in accord with accepted professional medical standards, but nevertheless are authorized by law or a government agency for use in testing, trials, or other studies on human patients, shall be considered experimental or investigational.” Given that this intervention is not in accord with accepted professional medical standards, even though FDA approved, it is considered experimental and investigational.

Discussion

17. In October 2016, Anthem denied respondent’s request for an ARPWave, indicating that the requested device was not medically necessary and is considered experimental/investigational for the treatment of MS and muscle spasticity and atrophy. In total, eight physicians evaluated respondent’s request for an ARPWave, comparing his clinical records and the applicable provisions of PERS Care EOC. Seven of the eight physicians determined that the ARPWave is not medically necessary and is experimental and investigational; a DME must be medically necessary and not experimental and/or investigational to be covered by the Plan. While MAXIMUS Physician #3 found the ARPWave to be medically necessary, he failed to cite any scientific references or peer-reviewed literature to support his findings. In addition, MAXIMUS Physician #3 inaccurately conflates the TENS device with the ARPWave; according to ARPWave, LLC, the technology is quite different.

18. In addition, Dr. Sun identifies several supplementary reasons to support Anthem’s findings, including: other managed care organizations do not cover the ARPWave; there is no mention of ARPWave in the Independent Medical Review database of the California Department of Managed Health Care; and there is no mention of ARPWave in the UpToDate or PubMed databases.

19. In the end, respondent failed to present sufficient medical evidence to support the use and coverage of an ARPWave for MS and muscle spasticity and atrophy. Whereas, CalPERS presented sufficient evidence to prove the ARPWave falls outside the PERS Care coverage.
LEGAL CONCLUSIONS

1. Jurisdiction for this proceeding exists under Government Code section 22848, which provides:

   An employee or annuitant who is dissatisfied with any action or failure to act in connection with his or her coverage or the coverage of his or her family members under this part shall have the right of appeal to the board and shall be accorded an opportunity for a fair hearing. The hearings shall be conducted, insofar as practicable, pursuant to the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3.

2. Respondent has the burden of establishing by a preponderance of the evidence that his benefits claim is within the scope of the coverage provided by the PERS Care health plan. (Dyer v. Northbrook Property and Casualty Ins. Co. (1989) 210 Cal.App.3d 1540, 1547; McCoy v. Board of Retirement (1986) 183 Cal.App.3d 1044, 1051.) CALPERS, the insurer, has the burden of showing that a claim falls within an exclusion in the policy. (Dyer v. Northbrook Property and Casualty Ins. Co., supra, 210 Cal.App.3d at p. 1547.) “To prevail, the insured must prove the existence of a potential for coverage, while the insurer must establish the absence of any such potential. In other words, the insured need only show that the underlying claim may fall within policy coverage; the insurer must prove it cannot.” (Smith Kandal Real Estate v. Continental Casualty Co. (1998) 67 Cal.App.4th 406, 414.)

3. “An insurance policy, like all contracts, is to be interpreted to effectuate the mutual intent of the parties.” (Id. at p. 415; see also Haynes v. Farmers Insurance Exchange (2002) 95 Cal.App.4th 588, 595.) Exclusionary provisions in an insurance policy must be “conspicuous, plain, and clear to be enforceable.” (Steven v. Fidelity & Casualty Co. (1962) 58 Cal.2d 862, 878.) “An insurer may select the risks it will insure and those it will not, and a clear exclusion will be respected. (Smith Kandal Real Estate v. Continental Casualty Co., supra, 67 Cal.App.4th at p. 415.) “However, an exclusion or limitation on coverage must be clearly stated and will be strictly construed against the insurer. If an exclusion ambiguously lends itself to two or more reasonable constructions, the ambiguity will be resolved against the insurer and in favor of coverage.” (Ibid.; see also Reserve Insurance Company v. Pisciotta (1982) 30 Cal.3d 800, 807-08.)

4. Under Government Code sections 22794 and 22796, the CalPERS Board is granted all powers reasonably necessary to carry out and enforce the provisions of the PEMHA, and to adopt necessary rules and regulations pertaining to the scope, content and standards for its health benefit plans. Under this authority, CalPERS has the discretion to exclude certain medical services from coverage pursuant to California Code of Regulations, title 2, section 599.510, subdivision (b)(5).

5. Health plans are required to provide an EOC to enrollees summarizing the conditions of the plan, including but not limited to, those concerning benefits, claims, and
payment of claims pursuant to California Code of Regulations, title 2, section 599.508, subdivision (a)(6).

6. Under the 2017 EOC, a DME must be medically necessary and not experimental or investigational. The medical evidence presented supports a determination that the ARPWave did not meet these requirements. Based on this determination, the denial by Anthem and CalPERS of respondent’s request for coverage complied with the terms of the PERS Care EOC.

7. Based upon the Factual Findings as a whole, cause exists under Government Code sections 22794 and 22796, to affirm the determination of CalPERS and Anthem, denying coverage for an ARPWave device.

ORDER

The determination by Anthem and CalPERS denying coverage for an ARPWave device for respondent is affirmed. The appeal filed by respondent Timothy E. Ramos is denied.

DATED: October 26, 2018

ERIN R. KOCH-GOODMAN
Administrative Law Judge
Office of Administrative Hearings