

<b>Case Number:</b>	CM15-0120472		
<b>Date Assigned:</b>	07/01/2015	<b>Date of Injury:</b>	07/22/2013
<b>Decision Date:</b>	08/04/2015	<b>UR Denial Date:</b>	06/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/22/2015

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Internal Medicine

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is 36 year old male who sustained an industrial injury on 7/22/13. Diagnoses are lumbar radiculopathy, Lumbar 4-5 herniated nucleus pulposus with stenosis, status post epidural injection- 9/9/14. In a progress report dated 3/12/15, a treating physician notes continued complaints of low back pain, which radiates to the left posterolateral thigh to the foot. Pain is rated as 6/10 and increases with sitting and standing and he has numbness. Previous treatment includes a left transforaminal epidural injection, which was done on 9/9/14 with 2 months of excellent relief. Now the injured worker complains of low back pain rated at 7/10 and left leg pain at 5/10. Medications are Neurontin, Motrin, and Flexeril. Objective exam is positive for spasms and positive triggers at bilateral L5, straight leg raise is positive on the left at 60 degrees, decreased sensation of the left lateral thigh, and strength is decreased at the left flexor hallucis longus. An MRI of the lumbar spine reveals L4-5 herniated nucleus pulposus with stenosis. Lumbar range of motion is flexion at 60 degrees, extension 15 degrees, right lateral 20 degrees and left lateral 15 degrees. The treatment plan is L4-5 epidural steroid injection, acupuncture, continue home exercise program, refill medications and wean as tolerated. In a home H-Wave compliance and outcome report dated 5/13/15 it is noted that the H-Wave was used for 30 days and has helped more than other treatment, medication was taken in conjunction with it and he is sleeping better, sleeping through the night. Pain level before use of the H-Wave is noted to be 8/10 and after is noted as a 40% improvement. The H-Wave treatments were once a day for 30-45 minutes 7 days a week. He also notes conservative care already tried as medication, transcutaneous electrical nerve stimulation and physical therapy. Work status on the

4/13/15 evaluation is noted as he is not working. A primary treating physician's narrative report dated 5/18/15 notes the treatment plan is to purchase a Home H-Wave Device System. The requested treatment is a home H-Wave device, purchase.

### **IMR ISSUES, DECISIONS AND RATIONALES**

The Final Determination was based on decisions for the disputed items/services set forth below:

#### **Home H-Wave Device, Purchase: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines H-Wave Stimulation (HWT) Page(s): 117-118.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous electrotherapy H-wave stimulation (HWT) Page(s): 117-118.

**Decision rationale:** Based on MTUS guidelines, H-wave therapy is not recommended as an isolated intervention, but a one-month home-based trial of H-Wave stimulation may be considered as a noninvasive conservative option for diabetic neuropathic pain (Julka, 1998) (Kumar, 1997) (Kumar, 1998), or chronic soft tissue inflammation if used as an adjunct to a program of evidence-based functional restoration, and only following failure of initially recommended conservative care, including recommended physical therapy (i.e., exercise) and medications, plus transcutaneous electrical nerve stimulation (TENS). In a recent retrospective study suggesting effectiveness of the H-wave device, the patient selection criteria included a physician-documented diagnosis of chronic soft-tissue injury or neuropathic pain in an upper or lower extremity or the spine that was unresponsive to conventional therapy, including physical therapy, medications, and TENS. (Blum, 2006) (Blum2, 2006) There is no evidence that H-Wave is more effective as an initial treatment when compared to TENS for analgesic effects. A randomized controlled trial comparing analgesic effects of H- wave therapy and TENS on pain threshold found that there were no differences between the different modalities or HWT frequencies. (McDowell2, 1999) [Note: This may be a different device than the H-Wave approved for use in the US.] Regarding tissue repair, another study suggests that low-frequency HWT may produce direct localized effects on cutaneous blood flow, a finding relevant for clinicians working in the field of tissue repair. (McDowell, 1999) The one-month HWT trial may be appropriate to permit the physician and provider licensed to provide physical therapy to study the effects and benefits, and it should be documented (as an adjunct to ongoing treatment modalities within a functional restoration approach) as to how often the unit was used, as well as outcomes in terms of pain relief and function. Rental would be preferred over purchase during this trial. Trial periods of more than one month should be justified by documentation submitted for review. While H-Wave and other similar type devices can be useful for pain management, they are most successfully used as a tool in combination with functional improvement. H-wave stimulation is a form of electrical stimulation that differs from other forms of electrical stimulation, such as transcutaneous electrical nerve stimulation (TENS), in terms of its waveform. While physiatrists, chiropractors, or podiatrists may perform H-wave stimulation, H-wave devices are also available for home use. H-wave stimulation is sometimes used for the treatment of pain related to a variety of etiologies, muscle sprains, temporomandibular joint dysfunctions or reflex sympathetic dystrophy. In fact, H-wave is used more often for muscle

spasm and acute pain as opposed to neuropathy or radicular pain, since there is anecdotal evidence that H-Wave stimulation helps to relax the muscles, but there are no published studies to support this use, so it is not recommended at this time. H-wave stimulation has also been used to accelerate healing of wounds, such as diabetic ulcers. H-wave electrical stimulation must be distinguished from the H-waves that are a component of electromyography. (BlueCross BlueShield, 2007) (Aetna, 2005) Recent studies: A recent low quality meta-analysis concluded that the findings indicate a moderate to strong effect of the H-Wave device in providing pain relief, reducing the requirement for pain medication and increasing functionality, with the most robust effect observed for improved functionality, suggesting that the H-Wave device may facilitate a quicker return to work and other related daily activities. The low quality rating for this "meta-analysis" is primarily because the numbers were dominated by results from studies that were not prospective randomized controlled trials, but instead were retrospective observational studies using a patient survey, the H-Wave Customer Service Questionnaire, without a prospective control group. More definitive results may be on the way. According to this study, "double-blinded studies of the H-Wave device are currently underway and results will be awaited with interest." (Blum, 2008) In this case, the patient had significantly documented success during his one-month trial with H-wave therapy as an additive to his other treatments. He has also tried and failed multiple other modalities to control his pain. Therefore, based on the MTUS guidelines and the evidence in this case, the request for Home H-wave Device, purchase, is medically necessary.