

Case Number:	CM15-0020275		
Date Assigned:	02/09/2015	Date of Injury:	05/18/2012
Decision Date:	04/14/2015	UR Denial Date:	01/07/2015
Priority:	Standard	Application Received:	02/03/2015

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: District of Columbia, Virginia
 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 (IW) is a 31-year-old female who sustained an industrial injury on 05/18/2012. She has reported pain in the knee with a numb spot over her knee cap and pain in her low back. Diagnoses include knee contusion, knee sprain/strain, and lumbar spine sprain/strain. Treatments to date include conservative care with a TENS (transcutaneous electrical nerve stimulation) unit, physical therapy and medications. She has recently been treating with an H-Wave device. A progress note from the treating provider dated 12/05/2014 indicates diffuse tenderness to palpation of the lumbar spine extending from L1 to L5 paraspinal muscles. Deep tendon reflexes were normal. Heel/toe walk was positive. Treatment plan includes medications as previously prescribed, physical therapy, biofeedback, and use of an H-wave device. On 01/07/2015 Utilization Review non-certified a request for DME: H Wave Device Purchase noting there was limited evidence that the IW received benefit from an e-stim and/or H-wave unit as part of therapy services prior to the date of service. In addition, there was no clear indication as to how this modality will impact functional status in a positive manner. The MTUS were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

DME: H Wave Device Purchase: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines H-Wave stimulation (HWT).

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

Decision rationale: Per MTUS: H-wave stimulation (HWT): Not recommended as an isolated intervention, but a one-month home-based trial of HWave 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 Hwave 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, orpodiatrists 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 a supposed 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 there acquirement 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) Per guidelines, this intervention would not be recommended. The patient received minimal benefit from this intervention.