

Case Number:	CM15-0035018		
Date Assigned:	03/03/2015	Date of Injury:	10/01/2004
Decision Date:	04/13/2015	UR Denial Date:	02/18/2015
Priority:	Standard	Application Received:	02/24/2015

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 is a 69-year-old male patient, who sustained an industrial injury on 10/01/2004. An orthopedic visit dated 01/26/2015 reported current medications as Norco 10/325MG, Tizanidine, Omeprazole and Terocin. The patient is status post injection without any relief from pain. The assessment noted unspecified disorders of burae and tendons in shoulder region. A request was made for a prescription of Norco 10/325MG #180 and Terocin lotion 205/.025-10-25%, H-wave machine and pads. On 02/18/2015, Utilization Review, non-certified the request, noting the Ca MTUS, Chronic Pain, Norco, Compound Ointment and the ODG, H-wave were cited. On 02/24/2015, the injured worker submitted an application for independent medical review of requested services.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 10/325mg #180 with 5 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Hydrocodone/Acetaminophen, Opioids, Weaning of Medications.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792
 Page(s): 75, 91,124-127.

Decision rationale: Per MTUS: Short-acting opioids: also known as "normal-release" or "immediate-release" opioids are seen as an effective method in controlling chronic pain. They are often used for intermittent or breakthrough pain. These agents are often combined with other analgesics such as acetaminophen and aspirin. These adjunct agents may limit the upper range of dosing of short-acting agents due to their adverse effects. The duration of action is generally 3-4 hours. Short-acting opioids include Morphine (Roxanol), Oxycodone (OxyIR, Oxyfast), Endocodone, Oxycodone with acetaminophen, (Roxilox, Roxicet, Percocet, Tylox, Endocet), Hydrocodone with acetaminophen, (Vicodin, Lorcet, Lortab, Zydone, Hydrocet, Norco), Hydromorphone (Dilaudid, Hydrostat). (Baumann, 2002) Per review of the clinical literature, the patient had chronic pain issues. Long-term usage of this medication would not be indicated and a weaning process should be initiated.

Terocin Lotion 2.5-0.025-10-25% #2 bottles with 5 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Terocin, Topical Lidocaine, Topical Capsaicin, Salicylate Topicals, Topical NSAIDs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792
Page(s): 28, 38, 105, 111. Decision based on Non-MTUS Citation
<http://www.drugs.com/pro/terocin.html>.

Decision rationale: Terocin is a topical anesthetic. It contains: Methyl Salicylate 25%, Capsaicin 0.025%, Menthol 10%, Lidocaine 2.50%. Per MTUS: Recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The number needed to treat in musculoskeletal conditions was 8.1. The number needed to treat for neuropathic conditions was 5.7. (Robbins, 2000) (Keitel, 2001) (Mason-BMJ, 2004) The results from this RCT support the beneficial effects of 0.025% capsaicin cream as a first-line therapy for OA pain. (Altman, 1994) Mechanism of action: Capsaicin, which is derived from chili peppers, causes vasodilation, itching, and burning when applied to the skin. These actions are attributed to binding with nociceptors, which causes a period of enhanced sensitivity followed by a refractory period of reduced sensitivity. Topical capsaicin is superior to placebo in relieving chronic neuropathic and musculoskeletal pain. Capsaicin produces highly selective regional anesthesia by causing degeneration of capsaicin-sensitive nociceptive nerve endings, which can produce significant and long lasting increases in nociceptive thresholds. (Maroon, 2006). Adverse reactions: Local adverse reactions were common (one out of three patients) but seldom serious (burning, stinging, erythema). Coughing has also been reported. See also CRPS, medications; Topical analgesics.

For stimulus-independent pain, Mexiletine, lidocaine patches and capsaicin are used but efficacy is not convincing. Methyl salicylate: Recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004) See also Topical analgesics; & Topical analgesics, compounded. In MTUS section addressing topical analgesics, it is recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists - agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The role of capsaicin is still not recommended for the chronic pain. It, being a part of terocin formulation, is not indicated. Therefore, this is not medically indicated for this patient's condition.

H-Wave Machine: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back - Lumbar & Thoracic (Acute & Chronic), H-wave stimulation (devices); Pain (Chronic), H-wave Stimulation (HWT).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792 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 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) This patient does not meet criteria for a one month trial of an H wave unit at this time, per review of clinical literature. Nor does he require the pads which accompany this unit. This would not be medically indicated as it would be part of isolated therapy and should be part of a functional restoration program.

H-Wave Machine Pads: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back - Lumbar & Thoracic (Acute & Chronic), H-wave stimulation (devices); Pain (Chronic), H-wave Stimulation (HWT).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792
Page(s): 117-118z.

Decision rationale: Per MTUS: H-wave stimulation (HWT) 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)

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