

Case Number:	CM15-0077204		
Date Assigned:	04/28/2015	Date of Injury:	08/27/2014
Decision Date:	05/28/2015	UR Denial Date:	03/23/2015
Priority:	Standard	Application Received:	04/22/2015

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: Montana

Certification(s)/Specialty: Preventive Medicine, Occupational 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 43 year old female nurse who sustained an industrial injury to the low back on August 27, 2014 while assisting a patient. The injured worker was diagnosed as having umbilical hernia and lumbar strain/sprain with radiculitis. Treatment to date has included medication and chiropractic care for the lumbar strain/sprain and surgical consultation for the umbilical hernia. A progress note dated February 25, 2015 notes that the injured worker complains of low back pain radiating to tail bone. Physical exam notes positive right straight leg raise. X-rays were reviewed. The plan includes Transcutaneous Electrical Nerve Stimulation (TENS) unit, and Voltaren ER 100mg #40.

IMR ISSUES, DECISIONS AND RATIONALES

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

Voltaren ER 100 mg, forty count: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non-steroidal anti-inflammatory drugs Page(s): 67 and 71. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Diclofenac.

Decision rationale: Voltaren (diclofenac) is a non-steroidal anti-inflammatory drug (NSAID). The MTUS and ODG guidelines note that NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. Diclofenac Sodium (Voltaren, Voltaren-XR) is not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients as did rofecoxib (Vioxx), which was taken off the market. According to the authors, this is a significant issue and doctors should avoid diclofenac because it increases the risk by about 40%. (McGettigan, 2011) Another meta-analysis supported the substantially increased risk of stroke with diclofenac, further suggesting it not be a first-line NSAID. (Varas-Lorenzo, 2011) (Schjerning, 2011) If using diclofenac then consider discontinuing as it should only be used for the shortest duration possible in the lowest effective dose due to reported serious adverse events. Post marketing surveillance has revealed that treatment with all oral and topical diclofenac products may increase liver dysfunction, and use has resulted in liver failure and death. Physicians should measure transaminases periodically in patients receiving long-term therapy with diclofenac. (FDA, 2011) In 2009 the FDA issued warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac sodium. (FDA, 2009) With the lack of data to support superiority of diclofenac over other NSAIDs and the possible increased hepatic and cardiovascular risk associated with its use, alternative analgesics and/or non-pharmacological therapy should be considered. With diclofenac even in small doses it increases the risk of cardiovascular events. They recommended naproxen as the NSAID of choice. In this case 40 Voltaren ER tablets are requested. The records do not document use of a first-line anti-inflammatory drug. As noted above, Voltaren is not recommended as first line due to increased risk profile. The request for Voltaren ER 100mg #40 is not medically necessary.

TENS unit purchase: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous electrotherapy Page(s): 114-116.

Decision rationale: The MTUS notes that transcutaneous electrical nerve stimulation (TENS) treatment is not recommended as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a

program of evidence-based functional restoration, for the conditions described below. While TENS may reflect the long-standing accepted standard of care within many medical communities, the results of studies are inconclusive; the published trials do not provide information on the stimulation parameters which are most likely to provide optimum pain relief, nor do they answer questions about long-term effectiveness. (Carroll-Cochrane, 2001) Several published evidence-based assessments of transcutaneous electrical nerve stimulation (TENS) have found that evidence is lacking concerning effectiveness. One problem with current studies is that many only evaluated single-dose treatment, which may not reflect the use of this modality in a clinical setting. Other problems include statistical methodology, small sample size, influence of placebo effect, and difficulty comparing the different outcomes that were measured. Criteria for the use of TENS: Chronic intractable pain (for the conditions noted above): Documentation of pain of at least three months duration. There is evidence that other appropriate pain modalities have been tried (including medication) and failed. A one-month trial period of the TENS unit should be documented (as an adjunct to ongoing treatment modalities within a functional restoration approach) with documentation of 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 - Other ongoing pain treatment should also be documented during the trial period including medication usage. A treatment plan including the specific short- and long-term goals of treatment with the TENS unit should be submitted. In this case there is no documentation of a one-month trial period of treatment with a TENS unit for the lumbar area with documentation of 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. A treatment plan including the specific short- and long-term goals of treatment with the TENS unit was not submitted. The current request for the purchase of one TENS unit is not consistent with the MTUS criteria and is not medically necessary.