

<b>Case Number:</b>	CM14-0196578		
<b>Date Assigned:</b>	12/04/2014	<b>Date of Injury:</b>	11/18/2002
<b>Decision Date:</b>	01/23/2015	<b>UR Denial Date:</b>	11/06/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/24/2014

### 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. The expert reviewer is Board Certified in Preventive Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Iowa. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

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

This is a 34 year old patient with date of injury of 11/18/2002. Medical records indicate the patient is undergoing treatment for annular tear with 4-5mm posterior central disc protrusion, annular tear with 3mm posterior central disc bulge at L2-3, 1-2mm posterior central disc bulge at L5-S1, mild facet arthropathy at L4-L5 and L5-S1 and annular tear and 5mm AP x 3mm cranial caudal broad posterior and inferior disc extrusion at L4-L5. Subjective complaints include pain in the lower back rated 6/10 and described as constant but the patient is no longer experiencing radiation into his legs. Objective findings include decreased range of motion and tenderness was present at the paraspinals, normal strength and sensation and deep tendon reflexes were normal. MRI of lumbar spine on 11/25/2013 revealed annular tear with 4-5 mm posterior central disc protrusion at L3-L4 with mild to moderate spinal stenosis; disc bulge with annular tear and 5mm anterior to posterior x 3mm cranial caudal broad posterior and inferior disc extrusion at L4-L5 with mild facet arthropathy results in mild spinal stenosis. The patient has moderate bilateral neural foraminal narrowing, disc extrusion causes mild mass effect on bilateral L5 nerves; disc bulge with annular tear with 3mm posterior central disc bulge at L2-L3 which indents the anterior thecal sac but does not result in significant spinal stenosis. There is 1-2mm posterior central disc bulge L5-S1 with evidence of spinal stenosis; mild facet arthropathy L4-L5, L5-S1; and disc desiccation with mild disc height loss L2-L3 through L5-S1. Treatment has consisted of physical therapy, home exercise program, acupuncture and Icy Hot. The utilization review determination was rendered on 11/06/14 recommending non-certification of Kera-Tek Gel, 4oz, TENS Unit (30-day trial) and 1 Lumbar Spine Support.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Kera-Tek Gel, 4oz:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Salicylate, Menthol. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back - Lumbar & Thoracic (Acute & Chronic)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesic Page(s): 105; 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Salicylate topicals, Topical analgesics

**Decision rationale:** Kera-Tek Gel is the brand name version of a topical analgesic medication containing menthol and methyl salicylate. ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "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." ODG only comments on menthol in the context of cryotherapy for acute pain, but does state "Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns, a new alert from the FDA warns." MTUS states regarding topical 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." The medical documents do not support the use of this topical compound agent. As such, the request for Kera-Tek Gel, 4oz is not medically necessary.

**TENS Unit (30-day trial):** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TENS, Chronic Pain (transcutaneous electrical nerve stimulation).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Interferential Current Stimulation, Transcutaneous electrotherapy Page(s): 54, 114-116, 118-120. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, TENS chronic pain (transcutaneous electrical nerve stimulation)

**Decision rationale:** MTUS states regarding TENS unit, "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." For pain, MTUS and ODG recommend TENS (with caveats) for neuropathic pain, phantom limb pain and CRPSII, spasticity, and multiple sclerosis. ODG further outlines recommendations for specific body parts: Low back: Not recommended as an isolated intervention Knee: Recommended as an option for osteoarthritis as adjunct treatment to a therapeutic exercise program Neck: Not recommended as a primary treatment modality for use in whiplash-associated disorders, acute mechanical neck disease or chronic neck disorders

with radicular findings  
Ankle and foot: Not recommended  
Elbow: Not recommended  
Forearm, Wrist and Hand: Not recommended  
Shoulder: Recommended for post-stroke rehabilitation  
Medical records do indicate conditions of the low back. ODG further details criteria for the use of TENS for Chronic intractable pain (for the conditions noted above):  
(1) Documentation of pain of at least three months duration  
(2) There is evidence that other appropriate pain modalities have been tried (including medication) and failed  
(3) 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  
(4) Other ongoing pain treatment should also be documented during the trial period including medication usage  
(5) A treatment plan including the specific short- and long-term goals of treatment with the TENS unit should be submitted  
(6) After a successful 1-month trial, continued TENS treatment may be recommended if the physician documents that the patient is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time. At this point purchase would be preferred over rental.  
(7) Use for acute pain (less than three months duration) other than post-operative pain is not recommended.  
(8) A 2-lead unit is generally recommended; if a 4-lead unit is recommended, there must be documentation of why this is necessary.  
The medical records detail a trial and failure of conservative treatment to include medication and physical therapy, waxing and waning of radiculopathy and chronic low back pain greater than 3 months. As such, the request for TENS Unit (30-day trial) is medically necessary.

## **1 Lumbar Spine Support: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 301. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back - Lumbar & Thoracic (Acute & Chronic)

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 301. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back ( Lumbar and Thoracic), Lumbar Support

**Decision rationale:** ACOEM states, "Lumbar supports have not been shown to have any lasting benefit beyond the acute phase of symptom relief." ODG states, "Not recommended for prevention. Recommended as an option for treatment. See below for indications. Prevention: Not recommended for prevention. There is strong and consistent evidence that lumbar supports were not effective in preventing neck and back pain. (Jellema-Cochrane, 2001) (van Poppel, 1997) (Linton, 2001) (Assendelft-Cochrane, 2004) (van Poppel, 2004) (Resnick, 2005) Lumbar supports do not prevent LBP. (Kinkade, 2007) A systematic review on preventing episodes of back problems found strong, consistent evidence that exercise interventions are effective and other interventions not effective, including stress management, shoe inserts, back supports, ergonomic/back education, and reduced lifting programs. (Bigos, 2009) This systematic review concluded that there is moderate evidence that lumbar supports are no more effective than doing nothing in preventing low-back pain. (van Duijvenbode, 2008)". ODG states for use as a "Treatment: Recommended as an option for compression fractures and specific treatment of spondylolisthesis, documented instability, and for treatment of nonspecific LBP (very low-

quality evidence, but may be a conservative option)." The patient is well beyond the acute phase of treatment and the treating physician has provided no documentation of spondylolisthesis or documented instability. As such the request for 1 Lumbar Spine Support is not medically necessary.