

Case Number:	CM14-0148553		
Date Assigned:	09/18/2014	Date of Injury:	07/28/1998
Decision Date:	10/20/2014	UR Denial Date:	08/19/2014
Priority:	Standard	Application Received:	09/12/2014

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 Physical Medicine and Rehabilitation and is licensed to practice in Georgia. 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:

The patient is a 59 year old male who was injured on 07/28/1988. The mechanism of injury is unknown. Treatment medications have included Anaprox, Motrin, Lodine, Flexeril, Robaxin, Soma, Zanaflex, Norco, Tylenol #3, Anxasia, Ultram, Fioricet, Elavil, Restoril, Ambien, Biotherm, and Gabapentin. Additional medications listed have included Prilosec, Zofran, Keflex. Additional prior treatments have included cervical epidural injections at C2-C3, C3-C4, C4-C5, and C5-C6 bilaterally on 07/29/2011, 08/26/2011, and 09/16/2011. He has also had L5-S1 and S1 lumbar transforaminal epidural injections bilaterally on 08/07/2012, 09/18/2012, and 10/12/2012. 06/18/2013 Neurosurgical evaluation noted worsening strength in the bilateral upper extremities. Documented were 5-/5 deltoids bilaterally, 4+/5 biceps and triceps on the right and 5-/5 on the left. Grip strength recorded as 4+/5 bilaterally. Opponens pollicis strength noted as 4/5 right, 4-/5 left. Interosseous muscles 4+/5 bilaterally. Diminished sensation was noted bilaterally at the C6 dermatome, and C7-C8 on the left. Reflexes noted as 1+ throughout in the upper extremities, and 2+ in the lower extremities. Results of a CT myelogram are reported as demonstrating progression of a collapse of the cervical spine, with both C6 screws having backed out anteriorly. The right C7 screw was reported to have backed out posteriorly, with "the whole construct" collapsed caudally into the vertebral body of T1, which left a marked diastasis into the vertebral body at C7 with screws impacting the posterior cortical margin of C7. Significant kyphosis was noted from C5-T1, with bowstringing of the spinal cord and noted compression on the cord. Marked foraminal stenosis was noted bilaterally at C5-C6, C6-C7, and C7-T1. Marked narrowing of the space for the esophagus with very tight compression of that structure was noted. Listed diagnoses included: 1. L4-S1 significant disc herniations with modic changes, marked facet hypertrophy, endplate deterioration, and high grade foraminal stenosis; 2. Very significant collapse of the cervical construct caudally with impaction into the

vertebral body of T1, loosening of the screws at C7 and C6 with backing out of the screws as well; 3. Very substantial dysphagia with multiple episodes of difficulty swallowing on a daily basis and near asphyxiation several times because of this. It was noted the patient had thus far undergone PT, chiropractic manipulation, acupuncture, and core strengthening, with failure noted of all of these conservative treatments. Surgery of the cervical spine was strongly recommended. A request was made for removal of the anterior cervical plate, removal of anterior osteophytes, vertebrectomy and corpectomy of C6 and C7 vertebrae with an expandable cage correction from C4-T1, as well as posterior fusion and decompression from C3-T2. Improved pain control was recommended. Lumbar surgery was also recommended, with a request for an L4-S1 posterior spinal fusion and decompression. 12/17/2013 Neurosurgical consultation report documented the following diagnoses: 1. L4-S1 significant disc herniations with modic changes, marked facet hypertrophy, endplate deterioration, and high grade foraminal stenosis; 2. Very significant collapse of the cervical construct caudally with impaction into the vertebral body of T1, loosening of the screws at C7 and C6 with backing out of the screws as well; 3. Very substantial dysphagia with multiple episodes of difficulty swallowing on a daily basis and near asphyxiation several times because of this. It was also mentioned the patient had osteomyelitis of the jaw and bacteremia. Recommendations were made the patient to have cervical surgery as soon as possible to decompress "the nerves and spinal cord." Additionally, it was noted the patient needed treatment for his infection prior to surgery. A request was also made for patient to have an orthopaedic second opinion regarding his right shoulder. 01/20/2014 progress report (PR) noted the patient presented with complaints of pain affecting the cervical spine. He also reported continued pain affecting the right shoulder in addition to pain the bilateral knees. It is noted the patient had been using a front-wheel walker for gait due to instability. Exam revealed tenderness to palpate on examination of the cervical spine. Global decreased range of motion in all planes was noted. Examination of the right shoulder revealed tenderness to palpation anteriorly and laterally. Global decreased range of motion in all planes was noted. Strength of unspecified muscle groups was 3+/5. Examination of the bilateral knees revealed tenderness to palpation bilaterally. Range of motion on the right revealed limited flexion and extension. Strength was recorded as 4/5. It was noted the patient ambulated with an antalgic gait pattern and unsteady gait with use of a front-wheel walker. Listed diagnoses included: 1. Closed head injury, status post cervical spine multilevel fusion with residuals; 2. Right shoulder chronic tearing at the anterior labrum; 3. Bilateral carpal tunnel syndrome; 4. Bilateral cubital tunnel syndrome; 5. Bilateral knee osteoarthritis; 6. Status post multiple falls secondary to loss of balance. No updated progress notes more recent than the 01/20/2014 progress note were provided. According to the 08/19/2014 UR, the patient was seen on 07/21/2014 for cervical spine pain, left shoulder pain, right shoulder pain, and bilateral knee pain. His pain ranged from a 7-9/10. He was taking Soma and hydrocodone daily and his symptoms were unchanged. His examination revealed decreased cervical spine range of motion with associated tenderness in the paraspinal and trapezius muscles bilaterally. His sensation was decreased at C5-C8. He had positive Neer's impingement, Hawkin's impingement, and severely limited range of motion with extension measured at 30 degrees, and flexion at 100 degrees. The patient had a diagnosis of right shoulder chronic tearing at the anterior labrum, bilateral carpal and cubital tunnel syndrome, bilateral knee osteoarthritis, status post multiple falls secondary to loss of balance and status post cervical spine multilevel fusion. A recommendation was made for compounded medications and consultation for a specialist for his cervical spine symptoms. Prior utilization review dated 08/19/2014 stated the request for Kera-Tek 4oz was not certified as there was a lack of documented evidence to support the request; Diclofenac/lidocaine 3/5% cream was denied as the compound is made of two substances that are not supported; Soma 350 mg #60 was not certified and a recommendation was made for weaning; Consultation with a specialist for the cervical spine was not certified as it was deemed not medically necessary.

IMR ISSUES, DECISIONS AND RATIONALES

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

Kera - Tek 4oz: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5527b965-615b-4eff-8597-8c3e2e626f61>

Decision rationale: Kera-Tek is a topical analgesic gel comprised of methyl salicylate and menthol. The Medical Treatment Utilization Schedule guidelines note that topical analgesics are largely experimental with few randomized controlled trials to determine efficacy or safety. 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. Many agents are compounded as monotherapy or in combination for pain control including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, alpha-adrenergic receptor agonists, adenosine, cannabinoids, cholinergic receptor agonists, gamma-agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factors. MTUS notes there is little to no research to support the use of many of these agents. MTUS also points out that "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Methyl salicylate is a non-steroidal anti-inflammatory. NSAIDs

administered topically have been shown to be more effective than placebo, and may be effective for treatment of osteoarthritis, chronic musculoskeletal pain, but not for neuropathic pain. Menthol is not recognized as a recommended medication for use as a topical analgesic. Based on the MTUS guidelines and criteria as well as the clinical documentation stated above, the request is not medically necessary.

Diclofenac/lidocaine 3/5% cream: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: The Medical Treatment Utilization Schedule guidelines note that topical analgesics are largely experimental with few randomized controlled trials to determine efficacy or safety. 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. Many agents are compounded as monotherapy or in combination for pain control including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, alpha-adrenergic receptor agonists, adenosine, cannabinoids, cholinergic receptor agonists, gamma-agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factors. California Medical Treatment Utilization Schedule (MTUS) notes there is little to no research to support the use of many of these agents. California MTUS also points out that "any

compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Lidocaine is recommended for treatment of neuropathic pain only. Other than Lidoderm patches, no other commercially approved topical formulation of lidocaine are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Based on the MTUS guidelines and criteria as well as the clinical documentation stated above, the request is not medically necessary.

Soma 350 mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (Soma).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 29; 63-64.

Decision rationale: The Medical Utilization Treatment Schedule notes that Soma is not recommended, and is specifically not intended for long-term use. It is a centrally acting skeletal muscle relaxant whose primary active metabolite, meprobamate, is a Schedule-IV controlled substance. Concern for abuse due to sedative and relaxant effects is high. Carisoprodol abuse has also been noted in order to augment the effects of other drugs, including tramadol (relaxation and euphoria), hydrocodone (effects reportedly similar to heroin), among others. If used, Soma is not recommended for treatment longer than 2-3 weeks. Medical records indicate the patient has been on Soma for not less than 4-years, without evidence in provided documents to indicate objective improvement in pain or function related to use of this medication. Based on the MTUS guidelines and criteria as well as the clinical documentation stated above, the request is not medically necessary.

Consultation with a specialist for the cervical spine: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) Chapter 7 Independent Medical Examinations And Consultations, page(s) 503 Official Disability Guidelines (ODG) , Indications for Surgery, Corpectomy; Decompression

Decision rationale: The American College of Occupational and Environmental Medicine notes that patients who are likely to benefit from surgery are those with evidence of severe spinovertebral disease including progressive neurologic deficit, or with severe, debilitating symptoms and physiologic evidence of specific nerve root or spinal cord compromise corroborated by appropriate imaging studies. The medical records clearly document neurologic impairment, with clear imaging findings and physiologic findings which all provide evidence that the documented cervical spine findings (failed hardware, vertebral collapse, foraminal narrowing, central canal stenosis, kyphotic deformity) which could very likely be the root cause of many of the patient's subjective complaints and objective exam findings. Regarding some of the specific surgical interventions suggested by the evaluating neurosurgeon, the Official Disability Guidelines (ODG) recommends decompression surgery to alleviate pain or neurological dysfunction caused by neural impingement. Among other indications, corpectomy is indicated for decompression of the spinal cord for degenerative spondylosis, as well as

for the correction of a fixed kyphotic deformity. Based on the ODG guidelines and criteria as well as the clinical documentation stated above, the request is medically necessary.