

Case Number:	CM15-0129910		
Date Assigned:	08/04/2015	Date of Injury:	05/15/2010
Decision Date:	09/22/2015	UR Denial Date:	06/08/2015
Priority:	Standard	Application	07/07/2015

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: New York

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 49-year-old female who sustained an industrial injury on 05-15-2010. Current diagnoses include status post right elbow lateral release with residual, and status post right thumb surgery. Previous treatments included medications, cortisone injections, surgical interventions, and physical therapy. Previous diagnostic studies included a right wrist MRI dated 02-19-2015, right shoulder and right elbow MRI with arthrogram dated 05-02-2014, and left shoulder MRI with arthrogram dated 05-30-2014. Initial injuries occurred when the worker was disinfecting a bed and her finger got stuck in a metal hole at the end of the bed, she stated her right thumb was pulled backwards with immediate onset of pain. Report dated 05-22-2015 noted that the injured worker presented for further medical evaluation of persistent symptoms despite surgical interventions. Complaints included right elbow and right thumb pain. Currently the injured worker is not working. Pain level was not included. Physical examination was positive for right elbow healed surgical scar, tenderness to palpation anteriorly and laterally, positive Cozen's test, right wrist arthroscopic scar, tenderness to palpation dorsal, palmar, and radial aspects, decreased range of motion, positive Tinel's and Phalen's tests, decreased motor strength right wrist and hand, and decreased sensation right upper extremity median nerve distribution. The treatment plan included prescriptions for Norco, Trepadone, flurbi (NAP) cream-LA, gabacyclotram, right elbow sleeve, hot and cold unit and TENS unit, urine toxicology was administered for medication monitoring, and referred for patient education web classes. Disputed treatments include hot & cold unit, lumbosacral brace, TENS unit, Norco 5/325mg #60, Trepadone #120 (1 bottle), flurbi (NAP) cream-LA (flurbiprofen 20%, lidocaine

5%, amitriptyline 5%) 180gm, gabacyclotram (gabapentin 10%, cyclobenzaprine 6%, tramadol 10%) 180gm, right elbow sleeve, urine toxicology, patient education (web classes), and physical therapy evaluation treatment, right elbow 3 x 4.

IMR ISSUES, DECISIONS AND RATIONALES

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

Hot & Cold Unit: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 10 Elbow Disorders (Revised 2007) Page(s): 27. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment in Workers Compensation, Elbow Procedure, Online Version updated 2/27/15.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee and Leg Chapter, Cold/heat packs.

Decision rationale: ODG states Continuous-flow cryotherapy units have been proven to decrease pain, inflammation, swelling, and narcotic usage. This meta-analysis showed that cryotherapy has a statistically significant benefit in postoperative pain control, while no improvement in postoperative range of motion or drainage was found. As the cryotherapy apparatus is fairly inexpensive, easy to use, has a high level of patient satisfaction, and is rarely associated with adverse events. ODG also state mechanical circulating units with pumps have not been proven to be more effective than passive hot and cold therapy. Guidelines are not met. The requested treatment Cold/Heat therapy unit is not medically necessary and appropriate.

Lumbosacral Brace: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 301.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter-Low Back-Lumbar & Thoracic (Acute & Chronic)-Lumbar supports.

Decision rationale: This request for Back Brace (Lumbar Back Support) is evaluated in light of the MTUS recommendations and Official Disability Guidelines (ODG). As per MTUS-ACOEM, lumbar supports have not been shown to have any lasting benefit beyond the acute phase of low back pain. Official Disability Guidelines (ODG) does not recommend it for prevention. There is strong and consistent evidence that lumbar supports were not effective in preventing neck and back pain. Lumbar supports do not prevent LBP. 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. This systematic review concluded that there is moderate evidence that lumbar supports are no more

effective than doing nothing in preventing low-back pain. Official Disability Guidelines (ODG) Recommends it 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. Among home care workers with previous low back pain, adding patient-directed use of lumbar supports to a short course on healthy working methods may reduce the number of days when low back pain occurs, but not overall work absenteeism. Acute osteoporotic vertebral compression fracture management includes bracing, analgesics, and functional restoration. Medical Records of the injured worker indicate chronic low back pain. As per submitted medical records and Guidelines cited, the back brace is not medically necessary and appropriate.

TENS Unit: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 300, Chronic Pain Treatment Guidelines TENS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous electrical nerve stimulation (TENS) Page(s): 115-116.

Decision rationale: As Per CA MTUS guidelines TENS unit is not recommended as a primary modality, but a one month home-based trial may be considered if used as an adjunct to a program of evidence-based functional restoration, with documentation of how often the unit was used. MTUS Guideline does support rental of this unit at the most for one month, but Medical Records are not clear if this injured worker has tried TENS unit in a supervised setting and were there any functional benefits. A treatment plan that includes the specific short and long-term goals of treatment with TENS unit cannot be located in the submitted Medical Records. The Requested Treatment TENS Unit is not medically necessary and appropriate.

Norco 5/325mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Functional improvement, Opioids section Page(s): 1, 74-96.

Decision rationale: The California MTUS chronic pain medical treatment guidelines recommend specific guidelines for the ongoing use of narcotic pain medication to treat chronic pain. "Recommendations include the lowest possible dose be used as well as ongoing review and documentation of pain relief, functional status, appropriate medication use and its side effects. It is also recommends that providers of opiate medication document the injured worker's response to pain medication including the duration of symptomatic relief, functional improvements, and the level of pain relief with the use of the medication." The CA MTUS Guidelines define functional improvement as "a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management and a reduction in the dependency on continued medical treatment." Therapies should be focused on functional

restoration rather than the elimination of pain. Medical record dated 01-15-2015 supports that the injured worker was prescribed Tylenol #3 by a different provider. The requesting provider did not include an evaluation of functional improvement with prior use of narcotic medications, there was no current list of prescribed medications, nor was there a rationale for why the injured worker required additional pain medications. Therefore, the request for Norco 5-325mg #60 is not medically necessary.

Trepadone #120 (1 bottle): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment in Workers Compensation, Pain Procedure Summary Online Version last updated 4/6/15.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain Chapter, Medical Food-Trepadone.

Decision rationale: Trepadone is a prescription medical food formulated for the dietary management of pain and inflammation related to joint disorders. Trepadone is formulated to increase the production of the neurotransmitters that inhibit neuronal firing and reduce animation. The California MTUS is silent regarding medical foods. The Official Disability Guidelines (ODG), does not recommend. "Trepadone is a medical food that is suggested for use in the management of joint disorders associated with pain and inflammation. It is a proprietary blend of L-arginine, L-glutamine, L-histidine, choline bitartrate, 5- hydroxytryptophan, L-serine, gamma-aminobutyric acid, grape seed extract, cinnamon bark, cocoa, omega-3 fatty acids, histidine, whey protein hydrolysate, glucosamine, chondroitin and cocoa. There is insufficient evidence to support use for osteoarthritis or for neuropathic pain. Medical foods are not recommended for treatment of chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain." According to the cited guidelines, Trepadone is not recommended. Therefore the request for Trepadone #120 (1 bottle) is not medically necessary.

**Flurbi (NAP) cream-LA (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 5%) 180gm:
Upheld**

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidocaine, Topical analgesics Page(s): 56, 111-113.

Decision rationale: According to the MTUS chronic pain medical treatment guidelines, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Flurbiprofen, a non-steroidal anti-inflammatory agent (NSAID), is not currently FDA approved for topical application. As topical flurbiprofen is not FDA approved, it is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tricyclic or SNRI anti-depressants, or an AED, such as gabapentin or Lyrica). There was no documentation of a diagnosis of post-herpetic neuralgia or that the injured worker has tried and failed other antidepressants and anticonvulsants, and at least one of the compounded medications are not recommended. In addition, the treating physician's request did not include the site of application, or directions for use. As such, the prescription is not sufficient and not medically necessary. Therefore, the request for Flurbi (NAP) cream-LA (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 5%) 180gm is not medically necessary.

Gabaclosetam (Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%) 180gm: 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: According to the MTUS chronic pain medical treatment guidelines, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Gabapentin is not recommended, there is no peer-reviewed literature to support use. Cyclobenzaprine is a muscle relaxant. The MTUS notes that there is no evidence for use of muscle relaxants as topical products. The documentation submitted did not support that the injured worker had failed a trial of oral antidepressant or antiepileptic medication and at least one of the compounded medications are not recommended. In addition, the treating physician's request did not include the site of application, or directions for use. As such, the prescription is not sufficient and not medically necessary. Therefore the request for Gabaclosetam (Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%) 180gm is not medically necessary.

Right Elbow Sleeve: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 10 Elbow Disorders (Revised 2007) Page(s): 2. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment in Workers Compensation, Elbow Procedure Summary Online Version.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 10 Elbow Disorders (Revised 2007) Page(s): 2. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Elbow Chapter, Splinting (padding).

Decision rationale: As per MTUS, in general, immobilization should be avoided. An exception is immediately after surgery where brief immobilization may be required. Wrist splinting is sometimes utilized. However, some experts believe splinting potentially contributes to elbow pain. When immobilization is utilized, range-of-motion exercises should involve the elbow, wrist, as well as the shoulder, to avoid frozen shoulder ("adhesive capsulitis"). Splinting (padding) is recommended for cubital tunnel syndrome (ulnar nerve entrapment), including a splint or foam elbow pad worn at night (to limit movement and reduce irritation), and/or an elbow pad (to protect against chronic irritation from hard surfaces). (Apfel, 2006) (Hong, 1996) Under study for epicondylitis. No definitive conclusions can be drawn concerning effectiveness of standard braces or splints for lateral epicondylitis. (Borkholder, 2004) (Derebery, 2005) (Van De Streek, 2004) (Jensen, 2001) (Struijs, 2001) (Jansen, 1997) If used, bracing or splitting is recommended only as short-term initial treatment for lateral epicondylitis in combination with physical therapy. (Struijs, 2004) (Struijs, 2006) Some positive results have been seen with the development of a new dynamic extensor brace but more trials need to be conducted. Initial results show significant pain reduction, improved functionality of the arm, and improvement in pain-free grip strength. The beneficial effects of the dynamic extensor brace observed after 12 weeks were significantly different from the treatment group that received no brace. The beneficial effects were sustained for another 12 weeks. (Faes, 2006) (Faes2, 2006) Static progressive splinting can help gain additional motion when standard exercises seem stagnant or inadequate, particularly after the original injury. Operative treatment of stiffness was avoided in most patients. (Doornberg, 2006) These results differ from studies testing standard bracing which showed little to no effect on pain. Guidelines for Right Elbow Sleeve are not met. The Requested Treatment: Right Elbow Sleeve is not medically necessary and appropriate.

Urine Toxicology: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment in Workers Compensation (TWC), Pain Procedure Summary, Urine Drug Testing (UDT).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug testing, On-going management of opioids, differentiation, dependence & addiction, Opioids screening for risk of addiction (tests) & opioids, steps to avoid misuse/addiction Page(s): 43, 78, 85-86, 90-91, 94-95, Postsurgical Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Urine Drug Testing (UDT).

Decision rationale: The California MTUS recommends drug testing as an option, "using a urine drug screen to assess for the use or the presence of illegal drugs." ODG state: (1) UDT is recommended at the onset of treatment of a new patient who is already receiving a controlled substance or when chronic opioid management is considered. Urine drug testing is not generally recommended in acute treatment settings (i.e. when opioids are required for nociceptive pain).

(2) In cases in which the patient asks for a specific drug. This is particularly the case if this drug has high abuse potential, the patient refuses other drug treatment and/or changes in scheduled drugs, or refuses generic drug substitution. (3) If the patient has a positive or "at risk" addiction screen on evaluation. This may also include evidence of a history of comorbid psychiatric disorder such as depression, anxiety, bipolar disorder, and/or personality disorder. See Opioids, screening tests for risk of addiction & misuse. (4) If aberrant behavior or misuse is suspected and/or detected. Review of Medical Records does not indicate substance abuse, noncompliance, or aberrant behavior. The treating provider does not provide any rationale about the need for Urine Toxicology. It is also determined that use of opioids is not medically necessary and appropriate. Guidelines are not met; therefore, the request is not medically necessary.

Patient education (web classes): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 44 and 45.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 15 Stress Related Conditions Page(s): 398.

Decision rationale: Education is a cornerstone of effective treatment. Patients may find it therapeutic to understand the mechanism and natural history of the stress reaction and that it is a normal occurrence when their resources are overwhelmed. Education also provides the framework to encourage the patient to enhance his or her coping skills, both acutely and in a preventive manner by regularly using stress management techniques. Physicians, ancillary providers, support groups, and patient-appropriate literature are all education resources. The treating provider notes do not outline specific topics about this request. There is no information about if such class was given to injured worker in the past and what was its outcome. Within the submitted medical records the determination cannot be made. Therefore, the Requested Treatment: Patient Education web class is not medically necessary.

Physical Therapy Evaluation Treatment, right elbow 3 x 4: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Physical Medicine Page(s): 98 and 99. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment in Workers Compensation, Elbow Procedure Summary.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Physical medicine Page(s): 98-99. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Elbow (Acute and Chronic).

Decision rationale: The California Chronic Medical Treatment Guidelines note that "active therapy is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy may require supervision from a therapist or medical provider such as verbal, visual and/or tactile instructions. Allow for fading of treatment

frequency (from up to 3 visits per week to 1 or less), plus active self-directed home physical medicine." The Official Disability Guidelines recommend, "up to 3 visits contingent on objective improvement documented (ie. VAS improvement of greater than 4). Further trial visits with fading frequency up to 6 contingent on further objectification of long term resolution of symptoms, plus active self-directed home PT." The provider request exceeds the recommended guidelines for initial physical therapy for the elbow. Therefore, the request for physical therapy evaluation treatment, right elbow 3 x 4 is not medically necessary.