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| Case Number: | CM15-0104816 | | |
| Date Assigned: | 07/20/2015 | Date of Injury: | 03/10/2011 |
| Decision Date: | 10/09/2015 | UR Denial Date: | 04/28/2015 |
| Priority: | Standard | Application Received: | 06/01/2015 |

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: California

Certification(s)/Specialty: Emergency 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 male, who sustained an industrial injury on 3/10/11. The injured worker was diagnosed as having bilateral elbow sprain/strain rule out joint derangement, bilateral wrist sprain/strain, avascular necrosis of the scaphoid of the right wrist, rule out carpal tunnel syndrome, anxiety disorder, other mood disorders, and nonorganic sleep disorder. Treatment to date has included acupuncture and medication. On 3/20/15 elbow pain was rated as 4/10 and wrist pain was rated as 3/10. On 4/20/15 elbow pain was rated as 3-4/10 and wrist pain was rated as 3/10. On 4/20/15 physical examination findings included normal range of motion in bilateral elbows. Range of motion was decreased in bilateral wrists. Tinel's, Phalen's, and Flicker's tests were positive in bilateral wrists. Sensation to pinprick and light touch was slightly diminished along the ulnar and median nerve distribution in bilateral upper extremities. Currently, the injured worker complains of bilateral elbow pain with muscle spasms and bilateral wrist pain with muscle spasms. The treating physician requested authorization for Fanatrex 25mg/ml oral suspension 420ml, a urine drug screen, Synapryn 10mg/ml oral suspension 500ml, Tabradol 1mg/ml oral suspension 250ml, Ketoprofen 20% cream 187g, Deprizine 15mg/ml oral suspension 250ml, Dicopanor 5mg/ml oral suspension 150ml, Terocin patches, a MRI of bilateral wrists, and a MRI of the left elbow.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fanatrex 25mg/ml oral suspension 420ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-epilepsy drugs (AEDs).

Decision rationale: The request is for the use of a medication in the category of an anti-epileptic drug (AED). These medications are recommended for certain types of neuropathic pain. Most of the randomized clinical control trials involved include post-herpetic neuralgia and painful polyneuropathy such as in diabetes. There are few trials which have studied central pain or radiculopathy. The MTUS guidelines state that a good response to treatment is 50% reduction in pain. At least a 30% reduction in pain is required for ongoing use, and if this is not seen, this should trigger a change in therapy. There also should be documentation of functional improvement and side effects incurred with use. Disease states which prompt use of these medications include post-herpetic neuralgia, spinal cord injury, chronic regional pain syndrome, lumbar spinal stenosis, post-operative pain, and central pain. There is inadequate evidence to support use in non-specific axial low back pain or myofascial pain. In this case, there is lack of documentation of adequate pain reduction for continued use. The records also do not reveal functional improvement or screening measures as required. As such, the request is not medically necessary.

Urine drug screen: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/Urine drug testing (UDT).

Decision rationale: The request is for a urine drug screen. The ODG states the following regarding this topic: Recommended as a tool to monitor compliance with prescribed substances, identify use of undisclosed substances, and uncover diversion of prescribed substances. The test should be used in conjunction with other clinical information when decisions are to be made to continue, adjust or discontinue treatment. This information includes clinical observation, results of addiction screening, pill counts, and prescription drug monitoring reports. The prescribing clinician should also pay close attention to information provided by family members, other providers and pharmacy personnel. The frequency of urine drug testing may be dictated by state and local laws. Indications for UDT: At the onset of treatment: (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. See Opioids, indicators for addiction & misuse. Ongoing monitoring: (1) If a patient has evidence of a “high risk” of addiction (including evidence of a comorbid psychiatric disorder (such as depression, anxiety, attention-deficit disorder, obsessive-compulsive disorder, bipolar disorder, and/or schizophrenia), has a history of aberrant behavior, personal or family history of substance dependence (addiction), or a personal history of sexual or physical trauma, ongoing urine drug testing is indicated as an adjunct to monitoring along with clinical exams and pill counts. See Opioids, tools for risk stratification & monitoring. (2) If dose increases are not decreasing pain and increasing function, consideration of UDT should be made to aid in evaluating medication compliance and adherence. In this case, a urine drug screen is not supported by the guidelines. This is secondary to inadequate documentation of risk level commensurate to the frequency of evaluation requested. As such, it is not medically necessary.

Synapryn 10mg/1ml oral suspension 500ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain.

Decision rationale: Tramadol is a pain medication in the category of a centrally acting analgesic. They exhibit opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Centrally acting drugs are reported to be effective in managing neuropathic type pain although it is not recommended as first line therapy. The side effect profile is similar to opioids. For chronic back pain, it appears to be efficacious for short term pain relief, but long term (>16 weeks) results are limited. It also did not appear to improve function. The use of tramadol for osteoarthritis is indicated for short term use only (< 3 months) with poor long-term benefit. In this case, the patient does not meet the qualifying criteria. This is secondary to the duration of use, with this medication being indicated on a short-term basis only. As such, the request is not medically necessary.

Tabradol 1mg/ml oral suspension 250ml: Upheld

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 Official Disability Guidelines (ODG) Pain (Chronic)/NSAIDs, specific drug list & adverse effects.

Decision rationale: The request is for the use of ketorolac intramuscular injection for pain relief. The MTUS guidelines are silent regarding this issue. The ODG guidelines state the following: Ketorolac (Toradol, generic available): 10 mg. [Boxed Warning]: The oral form is only recommended for short-term (up to 5 days) in management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation following IV or IM dosing, if necessary. This medication is not indicated for minor or chronic painful conditions. Increasing doses beyond a daily maximum dose of 40 mg will not provide better efficacy, and will increase the risk of serious side effects. The FDA boxed warning would relegate this drug to second-line use unless there were no safer alternatives. Dosing: Acute pain (transition from IV or IM) for adults < 65 years of age: 20mg PO followed by 10mg PO every 4 to 6 hours (max 40 mg/day). An oral formulation should not be given as an initial dose. (Toradol Package Insert) The FDA has approved a nasal formulation of ketorolac (Sprix) for short-term pain management. (FDA, 2010) As indicated above, this patient does not qualify for the use of ketorolac. This is secondary to the duration of use with the guidelines stating that it is not to be given for chronic painful conditions. As such, the request is not medically necessary.

Ketoprofen 20% cream 187g: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the compounded topical treatment contains an NSAID. Qualifying factors for this product is indicated by the following per the guidelines: The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as stated above, the patient would not qualify for the use of a topical NSAID. This is based on the diagnosis and treatment duration. As such, the request is not medically necessary.

Deprizine 15mg/ml oral suspension 250ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: The request is for the use of a medication in the class of an acid reducing medication. The guidelines do not specifically address or advise the use of an H2 blocker but does make recommendations regarding medications in the same category classified as proton pump inhibitors. This is usually given for patients with esophageal reflux, gastritis, or peptic ulcer disease. It can also be used as a preventative measure in patients taking non-steroidal anti-inflammatories for chronic pain which have side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically with a proton pump inhibitor or Misoprostol. Criteria for risk are as follows: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Due to the fact the patient does not meet to above stated criteria, the request for use is not medically necessary.

Dicopanol 5mg/ml oral suspension 150ml: Upheld

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 Official Disability Guidelines (ODG) Mental Illness and Stress/Diphenhydramine (Benadryl).

Decision rationale: The request is for the use of Diphenhydramine which is in the category of an antihistamine. The MTUS guidelines are silent regarding this topic. The ODG states the following regarding its use: Not recommended. See Insomnia treatment, where sedating antihistamines are not recommended for long-term insomnia treatment. The AGS updated Beers criteria for inappropriate medication use includes diphenhydramine. (AGS, 2012) Anticholinergic drugs, including diphenhydramine, may increase the risk for dementia by 50% in older adults. There is an obvious dose-response relationship between anticholinergic drug use and risk of developing dementia, but chronic use, even at low doses, would be in the highest risk category. While there is awareness that these drugs may cause short-term drowsiness or confusion, which is included in the prescribing information, there is no mention of long-term effects on cognition, and generally awareness of this issue is very low, and both the public and doctors need to be encouraged to use alternative treatments where possible. (Gray, 2015) As stated above, the use of this medication is not indicated for use in this patient for insomnia. There is inadequate documentation of the reasoning for its use for other indications. As such, the request is not medically necessary.

Unknown prescription of Terocin patches: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the compounded topical treatment contains an NSAID. Qualifying factors for this product is indicated by the following per the guidelines: The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordan, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. In this case, as stated above, the patient would not qualify for the use of a topical NSAID. This is based on the diagnosis and treatment duration. As such, the request is not medically necessary.

MRI of the bilateral wrists: Upheld

Claims Administrator guideline: Decision based on MTUS Forearm, Wrist, and Hand Complaints 2004.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Forearm, Wrist, & Hand (Acute & Chronic)/ MRI's (magnetic resonance imaging).

Decision rationale: The request is for an MRI of the wrist/hand. The Official Disability Guidelines state the following regarding this topic: Recommended as indicated below. While criteria for which patients may benefit from the addition of MRI have not been established, in selected cases where there is a high clinical suspicion of a fracture despite normal radiographs, MRI may prove useful. (ACR, 2001) (Schmitt, 2003) (Valeri, 1999) (Duer, 2007) Magnetic resonance imaging has been advocated for patients with chronic wrist pain because it enables clinicians to perform a global examination of the osseous and soft tissue structures. It may be diagnostic in patients with triangular fibrocartilage (TFC) and intraosseous ligament tears, occult fractures, avascular neurosis, and miscellaneous other abnormalities. Many articles dispute the value of imaging in the diagnosis of ligamentous tears, because arthroscopy may be more accurate and treatment can be performed along with the diagnosis. (Dalinka, 2000) (Tehranzadeh, 2006) For inflammatory arthritis, high-resolution in-office MRI with an average follow-up of 8 months detects changes in bony disease better than radiography, which is insensitive for detecting changes in bone erosions for this patient population in this time frame. (Chen, 2006) See also Radiography. Indications for imaging Magnetic resonance imaging (MRI): Acute hand or wrist trauma, suspect acute distal radius fracture, radiographs normal, next procedure if immediate confirmation or exclusion of fracture is required, Acute hand or wrist trauma, suspect acute scaphoid fracture, radiographs normal, next procedure if immediate confirmation or exclusion of fracture is required, Acute hand or wrist trauma, suspect gamekeeper injury (thumb MCP ulnar collateral ligament injury), Chronic wrist pain, plain films normal, suspect soft tissue tumor, Chronic wrist pain, plain film normal or equivocal,

suspect Kienback's disease, Repeat MRI is not routinely recommended, and should be reserved for a significant change in symptoms and/or findings suggestive of significant pathology. (Mays, 2008) In this case, the request is not indicated. This is secondary to poor documentation of qualifying diagnosis as listed in the guidelines. As such, the request is not medically necessary.

MRI of the left elbow: Upheld

Claims Administrator guideline: Decision based on MTUS Elbow Complaints 2007.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Elbow (Acute& Chronic)/MRIs.

Decision rationale: The request is for an elbow MRI. The Official Disability Guidelines state the following regarding this topic: Recommended as indicated below. Magnetic resonance imaging may provide important diagnostic information for evaluating the adult elbow in many different conditions, including: collateral ligament injury, epicondylitis, injury to the biceps and triceps tendons, abnormality of the ulnar, radial, or median nerve, and for masses about the elbow joint. There is a lack of studies showing the sensitivity and specificity of MR in many of these entities; most of the studies demonstrate MR findings in patients either known or highly likely to have a specific condition. Epicondylitis (lateral "tennis elbow" or medial in pitchers, golfers, and tennis players) is a common clinical diagnosis, and MRI is usually not necessary. Magnetic resonance may be useful for confirmation of the diagnosis in refractory cases and to exclude associated tendon and ligament tear. (ACR, 2001) See also ACR Appropriateness Criteria Indications for imaging Magnetic resonance imaging (MRI): Chronic elbow pain, suspect intra-articular osteocartilaginous body; plain films non-diagnostic, Chronic elbow pain, suspect occult injury; e.g., osteochondral injury; plain films - non-diagnostic, Chronic elbow pain, suspect unstable osteochondral injury; plain films non-diagnostic, Chronic elbow pain, suspect nerve entrapment or mass; plain films non-diagnostic, Chronic elbow pain, suspect chronic epicondylitis; plain films non-diagnostic, Chronic elbow pain, suspect collateral ligament tear; plain films non-diagnostic- Elbow pain, suspect biceps tendon tear and/or bursitis; plain films non-diagnostic, Repeat MRI is not routinely recommended, and should be reserved for a significant change in symptoms and/or findings suggestive of significant pathology. (Mays, 2008) In this case, the request is not supported by the guidelines. This is secondary to inadequate documentation of a qualifying diagnosis listed. Pending receipt of this information, the request is not medically necessary.

