

Case Number:	CM15-0086110		
Date Assigned:	05/08/2015	Date of Injury:	11/15/1999
Decision Date:	09/15/2015	UR Denial Date:	04/13/2015
Priority:	Standard	Application Received:	05/05/2015

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 58 year old male, who sustained an industrial injury on November 15, 1999. The injured worker's initial complaints and diagnoses are not included in the provided documentation. The injured worker was diagnosed as having status post right knee anterior cruciate ligament reconstruction in 2000, un-united fracture tibial spines of right knee, status post removal of staple right tibia, status post right knee arthroscopy with partial lateral meniscectomy and resection of synovial plica, and right knee degenerative joint disease, all surfaces. Diagnostic studies were not included in the provided medical records. Treatment to date has included opioid and muscle relaxant medications. On April 3, 2015, the injured worker complains of continued sharp right knee pain with popping, stiffness, swelling, and occasional giving out. The physical exam revealed moderate right knee joint effusion. The treatment plan includes the administration of an intramuscular injection Ketorolac 60mg with Xylocaine and prescriptions for Hydrocodone/APAP 5/325mg, Tramadol 50mg, Cyclobenzaprine 10mg, Ketoprofen 75mg, and Kera-Tek Gel.

IMR ISSUES, DECISIONS AND RATIONALES

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

Hydrocodone/apap 5/325mg, #30 no refill: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78 of 127.

Decision rationale: The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement, which should eventually lead to medication discontinuation. The records also do not reveal screening measures as discussed above for continued use of a medication in the opioid class. As such, the request is not certified.

Tramadol 50mg, #240, x4 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 80-83.

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 or indications. As such, the request is not certified.

Cyclobenzaprine 10mg, #30, x5 refills: Upheld

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

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

Decision rationale: The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most

LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate qualifying evidence for use of a muscle relaxant, the request is not certified.

Ketoprofen 75mg, #60, x5 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Inflammatory Page(s): 22.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67 and 68.

Decision rationale: The request is for the use of NSAIDS to aid in pain relief. NSAIDS are usually used to aid in pain and inflammation reduction. The MTUS guidelines states that for osteoarthritis 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, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen especially for patients with moderate to severe pain. There is no evidence to support one drug in this class over another based on efficacy. In particular, there appears to be no difference between NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects, with COX-2 NSAIDs having fewer GI side effects at the risk of increased cardiovascular side effects. The FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain and function. (Chen, 2008) (Laine, 2008) For back pain, NSAIDs are recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007) In this case, there is inadequate documentation of functional improvement to justify continued use, as the guidelines recommend the lowest dose for the shortest period of time. The significant side effect profile of medications in this class put the patient at risk when used chronically. As such, the request is not certified.

Keratex Gel 4oz (four) x 3 Refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Page(s): 105.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topicals, Compound Medication Page(s): 111-113 of 127.

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 lends 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 certified.

Ketorolac 60mg with Xylocaine IM (Retro 4/3/15): Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) 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 certified.