

Case Number:	CM14-0216193		
Date Assigned:	01/06/2015	Date of Injury:	09/19/2003
Decision Date:	03/04/2015	UR Denial Date:	11/26/2014
Priority:	Standard	Application Received:	12/24/2014

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. 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: Hawaii, California

Certification(s)/Specialty: Preventive Medicine, Occupational 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 patient is a 52-year-old male who sustained a work related injury to his lower back and legs on September 19, 2003 when lifting a 100 pound box onto a chest high pallet. The injured worker underwent L4-S1 decompression and fusion on January 22, 2009 and removal of hardware on October 15, 2012. He is diagnosed with persistent chronic back pain post fusion, stress/anxiety with depression and sleep disorder. The injured worker was re-evaluated on November 6, 2014 by the primary treating physician for continued back pain, bilateral leg pain with pins and needles sensation, neck pain and medication refills. According to the report the injured worker walks with an antalgic gait and uses an assistive device. Tenderness of the paraspinal musculature of the thoracic and lumbar regions with decreased sensation of the L4 and L5 dermatomes bilaterally was noted. Lumbar range of motion was documented as flexion 45 degrees, extension 10 degrees, right and left rotation 40 degrees each, and right and left tilt 20 degrees each. Waddell signs were negative. Sciatic nerve compression was negative. Recent and current treatment modalities were not documented. Current medications consist of Diclofenac, Gabapentin, Tizanidine, Norco, Tramadol and Cideflex. The injured worker is Permanent & Stationary (P&S) and currently not working. The physician has requested authorization for Diclofenac 75mg 1 by mouth twice a day prn #90 with 3 refills; Gabapentin 600mg 1 by mouth three times a day prn with 3 refills; Norco 10/325mg 1 by mouth every 6 hours prn #90; Tizanidine 4mg 1 by mouth two to three times/day prn #90 with 3 refills; Tramadol 50mg 1 by mouth every 6 hours prn #90 with 2 refills; Cideflex 1 by mouth twice a day #100 with 2 refills. On November 26, 2014 the Utilization Review denied certification for Diclofenac 75mg 1

by mouth twice a day prn #90 with 3 refills; Gabapentin 600mg 1 by mouth three times a day prn (unspecified quantity) with 3 refills; Tizanidine 4mg 1 by mouth two to three times/day prn #90 with 3 refills and Cideflex 1 by mouth twice a day #100 with 2 refills. Norco 10/325mg 1 by mouth every 6 hours prn #90 was modified to Norco 10/325mg #45 and Tramadol 50mg 1 by mouth every 6 hours prn #90 was modified to Tramadol 50mg #45. The citation utilized by the Utilization Review was the Medical Treatment Utilization Schedule (MTUS), Chronic Pain Guidelines on the individual medications requested. The decision process was based on the lack of objective functional improvement, no evidence of an implemented written pain agreement or previous toxicology reports regarding chronic opioid usage, and long-term usage of muscle relaxants and non-steroidal anti-inflammatory drugs (NSAIDs).

IMR ISSUES, DECISIONS AND RATIONALES

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

Diclofenac 75mg 1po BID pm #90 with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 67-72.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Pain (Chronic), Diclofenac

Decision rationale: Diclofenac is an NSAID. MTUS specifies four recommendations regarding NSAID use: 1) Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. 2) Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. 3) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. 4) Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. Importantly, ODG also states that diclofenac is "Not recommended as first line due to increased risk profile. If using diclofenac then consider discontinuing as it should only be used for the shortest duration possible in the lowest effective dose due to reported serious adverse events." The request is for #90 with 3 refills, which is not the "shortest duration possible" per guidelines. Given the risk profile of this medication, closer follow-up between refills is necessary. As such, the request for Diclofenac 75mg 1po BID pm #90 with 3 refills is not medically necessary.

Gabapentin 600mg q po TID prn with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 16-18.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs Page(s): 16-22. Decision based on Non-MTUS Citation Chronic Pain, Anti-epilepsy drugs (AEDs) for pain, Gabapentin (Neurontin)

Decision rationale: The MTUS considers Gabapentin as a first-line treatment for neuropathic pain and effective for the treatment of spinal cord injury, lumbar spinal stenosis, and post op pain. MTUS also recommends a trial of Gabapentin for complex regional pain syndrome. ODG states "Recommended Trial Period: One recommendation for an adequate trial with Gabapentin is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. (Dworkin, 2003) The patient should be asked at each visit as to whether there has been a change in pain or function. Current consensus based treatment algorithms for diabetic neuropathy suggests that if inadequate control of pain is found, a switch to another first-line drug is recommended." Additionally, ODG states that Gabapentin "has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain". The treatment notes do document neuropathic pain for which gabapentin is appropriate. However, the medical records do not indicate clear improvement of symptoms while on this medication that would warrant long-term extended medication refills without interim evaluation. As such, the request for Gabapentin 600mg q po TID prn with 3 refills is not medically necessary as written.

Norco 10/325mg 1 po q 6hrs prn #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-82.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Neck and Upper Back (Acute and Chronic), Low Back - Lumbar & Thoracic (Acute & Chronic), Shoulder, Pain, Opioids

Decision rationale: ODG does not recommend the use of opioids for neck, low back, and shoulder pain, except for short use for severe cases, not to exceed 2 weeks. The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. As such, the request for Norco 10/325mg 1 po q 6hrs prn #90 not medically necessary.

Tizanidine 4mg 1 po BID/TID prn #90 with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 63-65.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants, Zanaflex Page(s): 63-67.

Decision rationale: Zanaflex is the brand name version of tizanidine, which is a muscle relaxant. MTUS states concerning muscle relaxants Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (VanTulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Homik, 2004) Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. (Chou, 2004) According to a recent review in American Family Physician, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. (See2, 2008). MTUS further states, Tizanidine (Zanaflex, generic available) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. (Malanga, 2008) Eight studies have demonstrated efficacy for low back pain. (Chou, 2007) One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. (Malanga, 2002) May also provide benefit as an adjunct treatment for fibromyalgia. (ICSI, 2007). Refills are not appropriate for Zanaflex due to the need for medical monitoring. Additionally, the medical notes do not indicate improvement of pain or functional level. As such, the request for Tizanidine 4mg 1 po BID/TID prn #90 with 3 refills is not medically necessary.

Tramadol 50mg 1 po q 6hrs prn #90 with 2 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, Tramadol, Ultram. Decision based on Non-MTUS Citation Pain (Chronic) - Medications for acute pain (analgesics), Tramadol (Ultram)

Decision rationale: Tramadol is classified as central acting synthetic opioids. MTUS states regarding tramadol that "A therapeutic trial of opioids should not be employed until the patient

has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." ODG further states, "Tramadol is not recommended as a first-line oral analgesic because of its inferior efficacy to a combination of Hydrocodone/ acetaminophen." Medical records did not indicate goal setting, additionally; the medical records do not establish sufficient improvement of symptoms. The medical records also do not establish least reported pain, pain with and without medications. As such, the request for Tramadol 50mg 1 po q 6hrs prn #90 with 2 refills is not medically necessary.

Cideflex 1po BID #100 with 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) Page(s): 50.

Decision rationale: Regarding Glucosamine (and Chondroitin Sulfate), MTUS states: "Recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride" Cideflex is a combination product of chondroitin and glucosamine. The specific dosing and formulation per web search contains Glucosamine hydrochloride 500mg, Chondroitin Sulfate 400mg. Per MTUS chronic pain, "Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride". "The Glucosamine Chondroitin Arthritis Intervention Trial (GAIT) funded by the National Institutes of Health concluded that glucosamine hydrochloride (GH) and chondroitin sulfate were not effective in reducing knee pain in the study group overall; however, these may be effective in combination for patients with moderate-to-severe knee pain." "Compelling evidence exists that GS may reduce the progression of knee osteoarthritis. Results obtained with GS may not be extrapolated to other salts (hydrochloride) or formulations (OTC or food supplements) in which no warranty exists about content, pharmacokinetics and pharmacodynamics of the tablets". As Cideflex contains a component that is not advised (glucosamine hydrochloride), the product is thus not advised. The request for Cideflex 1po BID #100 with 2 refills is not medically necessary.